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ADDRESSING UNMET NEEDS IN WOMEN'S HEALTH

HEARING

BEFORE THE

SUBCOMMITTEE ON PUBLIC HEALTH

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

ON

EXAMINING WOMEN'S HEALTH ISSUES, INCLUDING THE ROLE OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES IN IMPROVING THE HEALTH OF WOMEN AND MAKING PREVENTION A CENTERPIECE

APRIL 25, 2002

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C O N T E N T S

STATEMENTS

APRIL 25, 2002

ADDITIONAL MATERIAL

ADDRESSING UNMET NEEDS IN WOMEN'S HEALTH

THURSDAY, APRIL 25, 2002

U.S. SENATE,
SUBCOMMITTEE ON PUBLIC HEALTH, OF THE COMMITTEE ON
HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:30 p.m., in room SD–430, Dirksen Senate Office Building, Hon. Hillary Rodham Clinton, presiding.

Present: Senators Clinton, Mikulski, Wellstone, Murray, and Frist.

OPENING STATEMENT OF SENATOR CLINTON

Senator CLINTON. The committee will come to order.

As many of you know, there is a lot of activity occurring today with respect to the energy legislation that we have been dealing with for some weeks, and there will be a series of votes starting at around 3 o'clock. A number of my colleagues are tied up in that as well as other pressing business, so I am going to get started.

We have a very large, interested crowd here, and this is "Take Your Daughter to Work Day," so this is a particularly apt subject for our hearing on this day, and it is a real pleasure to welcome all of you.

Less than 10 years ago, the Office of Research on Women's Health was created at the National Institutes of Health. I personally think that that was one of the earliest and best decisions of the Clinton Administration. At that time, we recognized that women's health issues needed and deserved more attention.

I believe that we have come quite a long way in fulfilling that recognition and awareness, but we still have a lot of work ahead of us.

I want to thank Senators Harkin and Kennedy for calling this hearing today. They clearly recognize, as I do, that our business is not finished. I also want to thank Senators Snowe, Harkin, and Mikulski for introducing a bill to establish an Office of Women's Health in every major Federal health agency.

We have some unfinished business and then some new business. Among the areas of new business, I think we have to pay particular attention to the intersection between women's health and the environment. I held a hearing on Long Island, because we have a higher than the national average rate of breast cancer on Long Is-

land, and there are other places in our country where that is also the case.

We do not know if there is an environmental link or cause that we are missing, but we are now committed to finding out what the answer might be. I have introduced an environmental health tracking bill, and I also appreciate greatly Senator Chafee's Breast Cancer and Environmental Research Act.

We know that many of our young people face challenges in developing healthy eating and exercise behaviors. Obesity is increasing in our country, and minority women are particularly affected, dying too early from diabetes and heart disease. We also know that women continue to suffer from eating disorders, constantly striving to be excessively thin, defining their values based on their dress size and too often dying in the process.

Senator Bingaman and I are introducing a bill that would attempt to prevent the serious array of eating and health-related problems by supporting research to identify the best ways to help young people, particularly young women, develop healthy eating habits.

Although we tend to focus on diseases that afflict women, we also have to remember the special role that women play as our caregivers, both in our families and in society. We are particularly concerned about the large number of women who find themselves in the so-called sandwich generation. Twenty-six million Americans care for an adult family member who is ill and disabled; the vast majority of them are women. Eighteen million children have a condition that places significant demands on their parental caregivers, again, mostly caregiving mothers. Four million Americans with mental retardation or a developmental disability live with their families.

These numbers are very high and I think not well-known among the general public. We often in America tend to think of the individual challenges facing our families as not shared necessarily by the larger society of which we are a part.

I know that there are many people who are concerned about the health effects that flow from the emotional and physical demands of caregiving, and Senators Snowe, Mikulski, Breaux and I will be introducing the Lifespan Respite Care Act next week, which we hope will begin to both define and deal with these challenges.

So there is a lot that we have to talk about today. We are going to try to get through all of our distinguished witnesses before what is called the "vote-a-rama" starts, which is where you have votes about every 10 minutes and you stay right there until the are done.

At this time I would like to submit statements from Senator Carnahan and Senator Chafee for the record.

[Prepared statements of Senators Carnahan and Chafee follow:]

PREPARED STATEMENT OF SENATOR CARNAHAN

Mr. Chairman, I would like to commend you for calling for this hearing and for your steadfast leadership on women's health issues.

I want to bring the committee's attention to a serious health problem that affects women during their reproductive years—uterine fibroids. At least twenty to thirty percent of all women aged 35

and older have symptomatic uterine fibroids that require treatment. This number rises to approximately fifty percent for African-American women.

Given that uterine fibroids affects millions of women and how little we know about it, I believe that it is important to increase research into the disease and also public awareness of it. I am proud to announce that I have introduced the Uterine Fibroids Research and Education Act of 2002, S. 2122.

I would like to recognize two members of this committee, Senator Mikulski and Senator Jeffords, who are co-sponsoring this legislation. Both are strong advocates for women's health. I appreciate their support on this important issue and look forward to working with them to move the legislation through the HELP Committee as soon as possible.

Uterine fibroids are a benign tumor that impacts the reproductive health of women, particularly minority women. If they go undetected or untreated, uterine fibroids can lead to childbirth complications or infertility, among other things.

For those who do seek treatment, the option prescribed most often is a hysterectomy. Uterine fibroids are the top reason for hysterectomies currently being performed in this country. A hysterectomy is a major operation—the average recovery time is six weeks. This is just the physical impact, the emotional impact lasts much longer.

We need to invest additional resources in research, so that there are more treatment options for women, including options less drastic than a hysterectomy. We also need to increase awareness of uterine fibroids, so that more women will recognize the symptoms and seek treatment. My legislation will provide a sustained Federal commitment to better understanding uterine fibroids.

It has two components. First, it authorizes $10 million for the National Institutes of Health (NIH) for each of four years to conduct research on uterine fibroids.

Second, the bill supports a public awareness campaign. It calls on the Secretary of the U.S. Department of Health and Human Services to carry out a program to provide information and education to the public regarding uterine fibroids. The content of the program shall include information on the incidence and prevalence of uterine fibroids and the elevated risk for minority women. The Secretary shall have the authority to carry out the program either directly or through contract.

This legislation has been endorsed by the Society of Interventional Radiology, the American College of Obstetricians and Gynecologists, the National Uterine Fibroids Foundation, the American College of Surgeons, and the National Medical Association.

This legislation will make a meaningful difference in the lives of women and their families across this country. I encourage the HELP Committee to support this important legislation. Thank you.

PREPARED STATEMENT OF SENATOR CHAFEE

Mr. Chairman, I am pleased to submit this testimony on behalf of S. 830, the Breast Cancer and Environmental Research Act. I am pleased that your committee is considering this important legis-

lation, which will establish research centers that would be the first in the nation to specifically study the environmental factors that may be related to the development of breast cancer.

According to the National Breast Cancer Coalition, an estimated 233,000 women in the United States will be diagnosed with breast cancer this year, and 40,000 women will die of this terrible disease. We owe it to these women who are diagnosed with this life-threatening disease to provide them with answers for the first time.

It is generally believed that the environment plays some role in the development of breast cancer, but the extent of that role is not understood. S. 830 will enable scientists to conduct more conclusive and comprehensive research to determine the impact of the environment on breast cancer. While more research is being conducted into the relationship between breast cancer and the environment, there are still several issues that must be resolved to make this research more effective.

There is no known cause of breast cancer. There is little agreement in the scientific community on how the environment affects breast cancer. While studies have been conducted on the links between environmental factors like pesticides, an individual's diet, and electromagnetic fields, no consensus has been reached. There are other factors that have not yet been studied that could provide valuable information. While there is much speculation, it is clear that the relationship between environmental exposures and breast cancer is not well understood.

There are challenges in conducting environmental research. Identifying links between environmental factors and breast cancer is difficult. Laboratory experiments and cluster analyses, such as those in Long Island, New York, cannot reveal whether an environmental exposure increases a woman's risk of breast cancer. Epidemiological studies must be carefully designed because environmental exposures are difficult to measure.

Coordination between the National Institutes of Health (NIH), the National Cancer Institute (NCI), and the National Institute of Environmental Health Sciences (NIEHS) needs to occur. NCI and NIEHS are the two institutes within the NIH that fund most of the research related to breast cancer and the environment; however, comprehensive information specific to environmental effects on breast cancer is not currently available.

S. 830 will establish eight research centers to study these potential links. These "Breast Cancer Environmental Research Centers" would provide for multi-disciplinary research among basic, clinical, epidemiological and behavioral scientists interested in establishing outstanding, state-of-the-art research programs addressing potential links between the environment and breast cancer. The NIEHS would award grants based on a competitive peer-review process. This legislation would require each Center to collaborate with community organizations, including those that represent women with breast cancer. S. 830 authorizes $30 million each year over the next five years for these grants.

Many scientists believe that certain groups of women have genetic variations that may make them more susceptible to adverse environmental exposures. We need to step back and gather evidence before we come to conclusions—that is the purpose of this

bill. People are hungry for information, and there is a lot of inconclusive data, some of which has no scientific merit whatsoever. We have the opportunity through this legislation to gather legitimate and comprehensive data from premier research institutions across the nation.

Finally, I would like to point out that S. 830 has an impressive list of 30 bipartisan cosponsors, and is the product of a very carefully crafted compromise negotiated between the Senate and House sponsors, the National Breast Cancer Coalition, and the National Institutes of Health. While one could argue that no product is perfect, a lot of thought went into the crafting of this legislation to ensure that all affected parties would be pleased with the outcome. At times, it was not an easy feat to produce a bill that the advocates and the Institute would both find acceptable, but we managed to achieve this goal after several meetings. I am happy to say that S. 830 is the product of these successful negotiations.

Mr. Chairman and members of the committee, I appreciate this opportunity to present this testimony on behalf of this important legislation, and I look forward to working with you in the future to ensure its passage in the Senate.

Senator CLINTON. I want to begin now with the first panel. We have with us Dr. Eve Slater, Assistant Secretary for Health at the Department of Health and Human Services. She is responsible for overseeing the Office of Women's Health at HHS.

We also have Dr. James S. Marks, who is also a master in public health. He is director of the National Center for Chronic Disease Prevention and Health Promotion at the Centers for Disease Control and Prevention. He oversees all chronic disease prevention programs, including the Wisewoman program.

Welcome to both of you, and thank you for taking on these public responsibilities.

Dr. Slater?

STATEMENTS OF EVE E. SLATER, M.D., ASSISTANT SECRETARY FOR HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND JAMES S. MARKS, M.D., DIRECTOR, NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. SLATER. Thank you very, very much. It is truly a pleasure to testify before you on behalf of this committee. I will state that this is actually my very first testimony before the Senate committee, and I am especially pleased to be testifying today on the topic of women's health. I think it is particularly appropriate and is again my pleasure.

My colleague, Dr. Marks, my team at HHS, and of course, the Secretary, are very dedicated to improving women's health and to building a platform, working with this committee, in order to make some of our objectives, in fact as many as we can, achievable.

In 2002, the Department of Health and Human Services will spend almost $70 billion on women's health. As you are well aware, just three agencies expend nearly 97 percent of these funds—the

NIH, HRSA, and the Centers for Medicare and Medicaid Services. They are responsible for over $61 billion in spending.

Doing the math, we can conclude that the majority of Federal expenditures on women's health support medical and public health services and research on diseases and conditions important to women.

The remaining three percent of this year's budget for women's health is divided among eight other offices and agencies, and those include the CDC, the Indian Health Service, FDA, and of course, the Office of Public Health and Science which I oversee. In 2002, the Office of Public Health and Science has budgeted over $68 million for women's health.

With strong support from this committee and others in Congress, the Department of Health and Human Services has contributed to a number of important successes in women's health over the past decade. For example, in 2000, nearly 85 percent of women over age 18 received a pap smear in the previews 3 years, and 75 percent of women over 50 received a mammogram.

These numbers represent not only the successful achievement of the Healthy People 2000 benchmarks for these preventive services, but most important, they represent saved lives. From 1992 to 1998, the rate of breast cancer mortality declined by an average of almost 2.5 percent each year, and a similar rate of decline was seen for cervical cancers. Programs such as the Breast and Cervical Cancer Early Detection Program at CDC have made important contributions to meeting these goals for low-income women across the country.

Additionally, the Secretary's and CMMS' focus on approving Medicaid waivers for treatment services means that low-income women now in 39 States have access to services that they did not have just 2 years ago. Women are not only living longer, they are living more healthy and productive lives in their later years.

Importantly, women today are becoming more informed and are appropriately asking for more details about the health issues that affect them. Our Department of Women's Health in the Office of the Secretary has encouraged this trend, and with support from this committee, they established the National Women's Health Information Center, the NWHIC, which targets public outreach to at-risk communities through neighborhood participation.

The NWHIC website actually has received on the order of 3,000 hits per month, which is I think a very impressive track record for that site.

We all know, and you especially know, that there is still much work to be done. Chronic conditions such as cardiovascular disease and diabetes are among the most prevalent, costly, and preventable of all health problems. Cardiovascular disease and its manifestations—heart attack, stroke—is the leading cause of death for U.S. women, and deaths alone understate the burden of the illness of cardiovascular disease.

Heart disease remains the leading cause of disability among working adults. Stroke alone accounts for disability among more than one million Americans, and almost 6 million hospitalizations each year are due to cardiovascular disease.

Diabetes, often linked to obesity, has reached epidemic proportions in this country. It is the fifth leading cause of death among women. More than one out of every 10 women in the United States displays signs of pre-diabetes or diabetes. According to recent data from the NCEP/ATP3 study, approximately one-quarter of all U.S. women display signs of the metabolic syndrome, which is a condition that predisposes to developing diabetes and cardiovascular disease. That number stands for 35 percent of Hispanic women; and in African American women, women outnumber men 57 percent in metabolic syndrome; among Hispanics, 27.6 percent more women than men have signs of this very serious risk-prone condition.

Among African American and Hispanic women in their mid-sixties, nearly one of every three——

Senator MIKULSKI [presiding]. Dr. Slater, please excuse me. I have just been advised that there will be votes through the afternoon. Could I ask you to summarize your testimony?

Dr. SLATER. Absolutely, Senator.

Senator MIKULSKI. And I am going to ask unanimous consent that your very informative full statement be included in the record.

Dr. SLATER. Thank you very much.

It is a pleasure to get to our focus. The focus of our department within HHS will be on preventing the truly preventable killers and debilitating diseases that affect women. These are chronic diseases. We will focus on cardiovascular disease, in particular stroke, with attention to lowering blood pressure and cholesterol; on cancer, with attention to increased screening and decreased smoking; on diabetes and obesity, with attention to improved diet and exercise; and HIV/AIDS.

These conditions were selected first because they represented the leading causes of morbidity and mortality in women; but second, disparities exist between men and women for these diseases either in treatment, incidence or prevalence, and finally, they are all preventable.

Additionally, as you are aware, the next Surgeon General's report will focus on the topic of osteoporosis, a disease that affects women disproportionately.

The mission of our office, to perhaps Senator Frist, who published a recent editorial in JAMA, is, after establishing goals and research priorities—and we agree with the Senator here—we must "move beyond input, means, and anecdotal evidence to develop new metrics to measure scientific advances and their causal relationship to improved outcomes." The focus is on prevention, on developing metrics to determine what works and to translate the best of science into improving these particular conditions that affect women.

Thank you very much, Senator. I will conclude there.

Senator MIKULSKI. Thank you, Dr. Slater. We could spend all afternoon just with you. Thank you for that excellent testimony.

[The prepared statement of Dr. Slater follows:]

PREPARED STATEMENT OF EVE E. SLATER, M.D.

Mr. Chairman, Senator Frist and members of the subcommittee, I am pleased to appear before you today to testify about the role of the Department of Health and Human Services in improving the health of women in the United States and to

highlight the Administration's plan to make prevention the centerpiece of the Departments activities on this important topic.

INVESTMENT IN WOMEN'S HEALTH

In 2002, the Department of Health and Human Services will spend almost $70 billion on women's health. Just three agencies expend nearly 97 percent of these funds—the National Institutes of Health, the Health Resources and Services Administration and the Centers for Medicare and Medicaid Services which is responsible for over $61 billion in spending. From this, we can conclude that the majority of Federal expenditures on women's health support medical and public health services and research on diseases and conditions important to women's health. The remaining three percent of this year's budget for women's health is divided among eight other offices and agencies—the Centers for Disease Control and Prevention, the Administration on Aging, the Administration for Children and Families, the Substance Abuse and Mental Health Services Administration, the Indian Health Service, the Agency for Healthcare Research and Quality, the Food and Drug Administration and the Office of Public Health and Science, which I oversee. In 2002, the Office of Public Health and Science has budgeted over $68 million for women's health.

SUCCESS IN WOMEN'S HEALTH

With strong support from this committee and others in Congress, the Department of Health and Human Services has contributed to a number of important successes in women's health over the past decade. In 2000, nearly 85 percent of women over age 18 received a pap smear in the previous three years and 75 percent of women over 50 received a mammogram. These numbers not only represent the successful achievement of the Healthy People 2000 benchmarks for these prevention services—but most importantly they also represent saved lives. From 1992–98, the rate of breast cancer mortality declined by an average of 2.4 percent each year and a similar rate of decline was seen for cervical cancer. Programs such as the Breast and Cervical Cancer Early Detection Program at CDC have made important contributions to meeting these goals for low-income women across the country. Additionally, the Secretary's and CMS' focus on approving Medicaid waivers for these services means that low-income women in 39 States now have access to these services that didn't just two years ago.

Women are not only living longer, they are living more healthy and productive lives in their later years. This allows them to remain fully engaged with family and friends and continue to make essential contributions to their communities and the nation as they age. Importantly, women today are becoming more informed and are asking for more details about the health issues that affect them. The Department has encouraged this trend, with support from this committee, by establishing the National Women's Health Information Center and targeting public outreach to at risk communities through neighborhood partnerships. Both of these efforts are managed through the Department's Office on Women's Health.

FOCUS ON PREVENTION

There is still much work to be done. Chronic conditions such as cardiovascular disease and diabetes are among the most prevalent, costly and preventable of all health problems. Cardiovascular disease and its manifestations such as heart attack and stroke are the leading cause of death for U.S. women. However, consideration of deaths alone understates the burden of cardiovascular disease. Heart disease is the leading cause of disability among working adults. Stroke alone accounts for disability among more than one million Americans and almost six million hospitalizations each year are due to cardiovascular disease.

Diabetes linked to obesity has reached epidemic proportions in this country. It is the fifth leading cause of death among women. More than one out of every ten women in the U.S. displays signs of prediabetes or diabetes. Twenty three percent of all U.S. women display signs of metabolic syndromes that predispose them to developing diabetes and cardiovascular disease—a number that stands at 35 percent for Hispanic women. Among African American and Hispanic women in their mid-sixties, nearly one out of every three suffers from diabetes and for Native American women this number may be as high as two out of every three.

The DHHS/OWH sponsors a national education campaign to promote healthy behaviors among minority women. *The Pick Your Path to Health Campaign* (PYPTH) offers practical, culturally appropriate action steps that women can take to improve their health. Through public/private partnerships, the Campaign's materials are distributed to local neighborhood groups and local media that are trusted by minority women. This year DHHS/OWH will launch a series of pilot programs in each of the

ten HHS regions, in which underserved women will be individually coached to develop their own personal action steps. In 2003, the campaign will be expanded to include rural women and women with disabilities.

The medical care costs of people with chronic diseases such as diabetes and cardiovascular disease account for over 70 percent of the $1 trillion spent nationally on health care each year. Effective prevention measures exist today to substantially curtail illnesses, disabilities and unnecessary or early deaths caused by these chronic illnesses and other preventable diseases.

THE OFFICE ON WOMEN'S HEALTH

President Bush and Secretary Thompson have made prevention a cornerstone of the nation's health agenda. During the announcement of his candidate for Surgeon General on March 26, 2002, the President reiterated his prevention message, noting, "Simple improvements in diet and exercise would result in dramatic improvements in America's health." The Office of the Surgeon General, the public health service corp and the Centers for Disease Control and Prevention are key players in the development and implementation of disease prevention strategies. On women's health, The Office on Women's Health in the Office of Public Health and Science will be responsible for seeing that health promotion and disease prevention goals are met for women.

The Office on Women's Health both runs programs that target women and also helps to coordinate the research, health promotion and disease prevention strategies of offices and agencies throughout the Department of Health and Human Services.

As part of implementing the President's and Secretary Thompson's health agenda, the Office on Women's Health is refining its performance goals to focus on activities that will result in measurable reductions in the rate of preventable diseases in women over the next few years. Initially, the office will focus on cardiovascular disease, cancer, diabetes and HIV/AIDS. These diseases were selected because, first, they represent leading causes of morbidity and mortality in women, second, disparities exist between men and women for these diseases—either in treatment, incidence or prevalence—and finally, they are all preventable.

THE ACTION PLAN

The keys to achieving these goals is to understand what strategies and interventions work to prevent these diseases in women and to ensure that proven and effective measures are deployed by the Department and replicated throughout the country. The Department, with the Office on Women's Health acting to help coordinate these efforts, will be identifying successful, evidenced based prevention and treatment strategies, promoting innovations based on new research, replicating successful models and disseminating information about these successful interventions to other public and private partners. Particular attention will be given to those models that successfully address health disparities seen among racial and ethnic minorities.

The Department's effort to reduce cardiovascular disease in women is a helpful illustration of this model. Today, the Agency for Healthcare Research and Quality is supporting work to understand why women are not treated as aggressively for cardiovascular disease as men and to determine which interventions result in the best outcomes for women suffering from cardiovascular disease. The Health Resources and Services Administration is helping to promote quality health care services among health professionals who serve populations of women in need, and CDC and HRSA have joined as partners to implement the WISEWOMAN program which provides low income women with risk factor screening, intervention services and medical referrals. Finally, the Office on Women's Health supports tailored public outreach, including the "*For your heart*" public education program and a partnership effort with the Association of Black Cardiologists and African American churches to bring health and prevention messages to women at high risk for cardiovascular disease.

In these efforts—we capture the essential elements of the Department's vision: research to understand what works and what does not; programs to bring this information to health professionals who are providing medical care and prevention services; and public outreach efforts to inform women about effective health behaviors and medical interventions.

In the future, the Department can do more to coordinate this bench to hearthside translation. For instance, recent exciting studies supported by NIH indicate that there are both protein markers and genetic ones that could help physicians identify women who are at high risk for poor outcomes from cardiovascular disease. If these early findings hold up to additional studies, we would then want to make sure this knowledge is incorporated into other HHS programs on women's cardiovascular dis-

ease. Over the next year, the Office on Women's Health will develop mechanisms to track new health and research findings, help promote assessments of their effectiveness and ensure this knowledge is disseminated within and outside the Department.

PROGRAM ACTIVITIES

I will now highlight a few examples of women's health program activities across HHS. Several broad initiatives among the agencies target multiple related health issues and I will cover these first.

Cardiovascular Disease

During the last 3 years, several members of Congress have asked DHHS/OWH and other agencies in the Department to review and develop programs to stem the risk of cardiovascular disease in women. The DHHS/OWH has collaborated with the American Heart Association in the development of a tailored heart disease prevention interactive website program, accessible through the National Women's Health Information Center, entitled, *"For Your Heart."* A tailored story and message are given to a woman based upon her self-identified race/ethnicity, behavioral risk factors, and stage in changing these factors.

The OWH also is partnering with the Association of Black Cardiologists (ABC) Center for Women's Health. The initiative will incorporate cardiovascular health education programs in churches with large African American populations, with the ultimate goal of reducing cardiovascular mortality and morbidity among women.

Two years ago, the AHRQ women's program launched an ongoing collaborative research initiative to understand why women receive less aggressive treatment for heart disease than do men, and what is known about the use and effectiveness of diagnostic testing and treatment of heart disease and stroke in women. The initiative involves representatives from several DHHS agencies, including the NIH Office of Research on Women's Health (ORWH) and the NHLBI, as well as the DHHS/OWH. Private sector partners include the American Heart Association, the Jacobs Institute on Women's Health, the Society for Women's Health Research, WomenHeart, and a number of professional organizations.

AHRQ and NIH/ORWH are also co-funding development of an evidence report at Stanford University and the University of California/San Francisco that is systematically reviewing the literature on cardiovascular disease as it specifically relates to women. It will establish a baseline for what is currently known (or not known) about the diagnosis and treatment of women with heart disease, as well as identify gaps in the scientific information on optimum care for women.

AHRQ also is conducting a cardiovascular care study which compares treatments and prevention services provided to men versus women (and minorities) in a large managed care organization. The results will be used to develop better benchmarks for care to women and minorities.

Diabetes

In May 2002, the Food and Drug Administration's Office on Women's Health (OWH) will launch *Take Time To Care About Diabetes.* This program will be cosponsored by the National Association of Chain Drug Stores (NACDS) and the American Diabetes Association (ADA). This campaign, following on the success of the award winning campaign *"Take Time to Care: Use Medicines Wisely,"* leverages extensive resources, infrastructure, and visibility through its partnerships with outside organizations, thus greatly enhancing the impact and effectiveness of the effort by FDA and HHS.

The campaign materials will consist of a brochure with background information, key messages, risk assessment questions, and a recipe booklet with meal ideas for diabetics. These materials will be distributed in partnership with local health organizations, pharmacies, senior centers, religious groups, universities, women's groups, and many others. Minority communities will be reached through several professional nursing associations.

Other HHS agencies are providing program assistance to FDA. The National Institutes of Health will supply Community Outreach Kits prepared by the National Diabetes Education Program for use by local organizations, the Centers for Disease Control and Prevention will provide an information pack on Women and Diabetes, covering each stage of a woman's life; the Centers for Medicare and Medicaid Services (CMS) will feature CMS comprehensive information about Federal benefits for diabetics on their website; the Indian Health Service will distribute campaign materials through selected Indian Health clinics in urban and reservation areas nationwide; and the Administration on Aging will distribute campaign materials through State units on aging, area agencies on aging, and Indian Tribal Organizations.

The NIH/ORWH supports a number of research grants in the area of Diabetes Prevention. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) currently has the Diabetes Prevention Program (DPP). This multi-centered randomized trial is designed to determine whether type 2 diabetes can be prevented or delayed in a population of high-risk individuals. Included in the high-risk population are women with a history of gestational diabetes mellitus (GDM) and individuals with impaired glucose tolerance.

OBESITY

The NIH has a very active and well-coordinated program of research on obesity that involves many institutes and centers. Examples of some current research avenues include: the genetic underpinnings of obesity; the molecular and neuroendocrinological regulation of food intake, energy expenditure, and fat storage; epidemiological studies to help understand the etiologies, interrelationships, course, and health effects of overweight and obesity and weight change among children and pregnant women; prevention studies targeted at the population level with special emphasis on high risk populations; and intervention studies including modification of behavior, activity and dietary patterns and the use of pharmacological agents.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has initiated a major education/translation activity focused on the topic of overweight and obesity. This initiative includes a national information service, the Weight-control Information Network (WIN), which provides health professionals and consumers with science-based material on obesity, weight control, and nutrition. WIN provides fact sheets, brochures, article reprints and conference and workshop proceedings. Additionally, a quarterly newsletter for health professionals is disseminated featuring the latest information from NIH and other organizations on obesity and related topics.

CDC, as the nation's "prevention" agency, supports chronic disease programs in State Health Departments, and supports State and Local Departments of Education to establish school-based prevention programs. CDC also supports surveillance to measure disease burden, identifies populations at risk, targets program efforts, and evaluates program effectiveness; educates the public and providers; and invests in research to evaluate and improve programs. CDC's chronic disease program WISEWOMAN provides high blood pressure and cholesterol screening and, in follow-up, intensive dietary and physical activity interventions for high-risk women.

HRSA, the Department's "access" agency, has created the Diabetes, Asthma and Cardiovascular Collaboratives. Education regarding healthy nutrition and regular physical activity are integral parts of these collaborative training and services models. Partnerships with local recreational departments, grocery stores, restaurants and fitness centers are also encouraged in the Collaborative care model.

HRSA's *Innovative Approaches to Promoting Positive Health Behaviors in Women* program identifies women in communities who may not seek health care and develops interventions for them to stimulate positive health behavior practices.

DOMESTIC VIOLENCE

Violence against women does not discriminate: it spans all racial, age, and economic boundaries. One in four women report that they have been victims of violence or stalking by a spouse, partner, or date. Violence against women is a leading cause of injury for American women between the ages of 15 and 54, increasingly a major public health issue for the United States. These acts of violence take several forms, including spousal and domestic partner violence, sexual assault and abuse, rape, incest, and elder abuse. Today there is much more awareness that violence against women is a major problem in our country, but this increased awareness has not yet translated into measurable decreases. Almost one-third of American women murdered each year are killed by their current or former partners, often a husband. And sadly, many children suffer or witness abuse in their homes, which can spawn legacies of violence for families across America. Violence at home often spills over into schools and places of work, and it affects people from every walk of life.

The HHS Violence Against Women Steering Committee, under the leadership of DHHS/OWH, coordinates the Department's responses to research needs, program implementation, service provision, and crisis intervention. This committee has proposed and coordinated department-wide budget initiatives, hosted seminars, and proposed actions to address evolving needs. They develop the bi-annual HHS Progress Report to the Secretary presented at the National Advisory Council on Violence Against Women. The Council is a presidentially appointed council consisting of experts in the fields of domestic violence and sexual assault, it is co-chaired by the Attorney General and the Secretary of Health and Human Services. The Depart-

ment's Violence Against Women Steering Committee is instrumental in assuring that the recommendations from the Council are implemented where possible throughout the Department.

One of the major reasons that health care providers give for not screening patients for domestic violence is their belief that they have no ability or training to assist patients who disclose that they are victims of violence. To test this barrier and overcome the reluctance of the health care system to offer screening and intervention programs, even simple ones that refer patients to community social resources, AHRQ is supporting a series of studies to assess the impact of health care interventions on the women they are intended to serve. The Agency's work is also exploring other aspects of providing health care services, including the use of health codes, reimbursement levels, and better use of technologies and information systems. Last year, AHRQ joined with the Family Violence Prevention Fund to develop a DHHS Visiting Scholar in Domestic Violence, the first such program to be offered by a DHHS agency. The Scholar Program brought a researcher to AHRQ for a year to assist in shaping a long-term research agenda that would be responsive to the needs of the private sector.

On an ongoing basis, HRSA's Area Health Education Centers (AHECs) provide training to primary care professionals in how to identify and treat spousal and domestic partner violence among patients. HRSA also provides support for primary care and clinical specialist programs to prepare nurses at an advanced level to care for women's unique health care needs. Finally, HRSA's Geriatric Education Centers (GECs) provide training to geriatric healthcare professionals to identify types of abuse and neglect in the elderly, assess at-risk patients and their families, and provide case management for victims of violence.

In addition, HHS regional Offices on Women's Health have been active in training health care professionals in identifying, treating and referring patients who are victims of family violence. For example, the Region X Women's Health Committee has been working with the Washington State Department of Health Perinatal Partnership Against Domestic Violence (PPADV), which seeks to train medical providers in identifying patients who are victims of family violence.

MATERNAL ORAL HEALTH

The National Institute of Dental and Craniofacial Research (NIDCR) at the National Institutes of Health (NIH) supports research addressing the link between the mother's oral health and the health of their infants/toddlers on two major areas, dental caries (cavities) and periodontal disease (gum disease).

The NIH/ORWH and the National Institute of Dental and Craniofacial Research (NIDCR) have a study underway that will evaluate whether periodontitis is a risk factor for adverse pregnancy outcomes—by adding an oral component to the ongoing Project Viva, a prospective study of 6,000 pregnant women, to evaluate this association. Maternal infection during pregnancy has been demonstrated to play an important role in etiology of preterm delivery. Periodontal infection can serve as a reservoir of gram negative anaerobic organisms and their products, and proinflammatory mediators which could target the placental membranes via systemic circulation, thus leading to preterm delivery or fetal growth restriction.

PUBLIC INFORMATION AND EDUCATION

Today's women lead complex lives and are sometimes overwhelmed by the amount of health information and misinformation in the media and on the Internet when they seek details about the health issues that affect them. The Department's National Women's Health Information Center (NWHIC), managed by the DHHS Office on Women's Health, provides both Internet (www.4woman.gov) and telephone access (1–800–994–WOMAN or TTD: 1–888–220–5446) to reliable noncommercial health information for women. NWHIC offers a single point-of-entry to over 4,000 publications, the vast majority from Federal agencies and 1,600 organizations on more than 800 health topics; eight specialty sections, including women with disabilities, healthy pregnancy, violence against women, breastfeeding, young women's health, and a Spanish-language section, 150 frequently asked questions (FAQs); national health education campaigns; a calendar of events; daily women's health news; and online journals and dictionaries. It currently averages over 6 million hits and 350,000 individual visitors to the web site and an additional 3000 phone inquiries per month. Women and their families can trust the information they find on NWHIC about all of their women's health issues.

LOOKING AHEAD

In my over thirty years in medicine and health research, I—like each of you—have seen incredible advances in our understanding of disease and our ability to target interventions to improve health. With Congress' generous support of biomedical and health research, strongly supported by this Administration, we are poised to reap enormous benefits for citizens of our country. However, what we have learned through research must be translated into medical practice and to the actions and activities of individual citizens. The Administration welcomes your focus on women's health and looks forward to working with you to develop targeted but flexible strategies that can continue to achieve the goal of improving the health and welfare of women in the United States.

That concludes my testimony. At this time I would be happy to answer questions from the subcommittee.

Senator MIKULSKI. I am also going to follow my own encouragement and not present an opening statement but just ask unanimous consent that it be included in the record. I know you would find me equally as mesmerizing, but we will put me aside.

[The prepared statement of Senator Mikulski follows:]

PREPARED STATEMENT OF SENATOR MIKULSKI

INTRODUCTION

Women's health needs have traditionally been overlooked and underfunded.

As recently as 10 years ago, women were excluded from medical research but the results of these research studies were applied to both women and men. This neglect put women's health and lives at risk.

I fought to make sure women were included in research studies and clinical drug trials. These efforts have paid off. We have made great strides on women's health in the last decade. Now this committee is looking to the future. I am pleased the committee will be considering women's health bills in May. I am the lead cosponsor of the Women's Health Office Act to make Women's Health Offices at the Department of Health and Human Services permanent. I am also a cosponsor of the WISEWOMAN Expansion Act that Senator Frist has sponsored to make sure low-income women have access to screenings for cardiovascular disease and osteoporosis.

I am also a proud cosponsor of SMART MOMS, a bill to address the disturbing fact that the United States ranks 20th out of 49 countries in maternal deaths.

I am fortunate to be here today with one of the great Galahads for women's health—Senator Harkin. From mammograms to maternal health, the women of this country owe a tremendous debt of gratitude to Senator Harkin for his leadership and commitment to women's health.

WHAT IS THE PROBLEM?

Women and men have different bodies and different health care needs. Some diseases—like ovarian cancer—affect only women. Some diseases are far more common in women than in men. High blood pressure is two to three times more common in women than men. Women are four times more likely than men to develop osteoporosis.

Women often use the health care system differently from men. Women make ¾ of all health care decisions in the U.S. The num-

ber of uninsured women has grown three times faster than the number of uninsured men over the past five years.

For years, despite these differences, men's health needs set the standard for our health care system and our health care research. I was appalled to learn that women were excluded from medical research because our hormone cycles complicated the results. This is no reason to put women's health at risk. The important differences between men's and women's health needs must be addressed in an ongoing, comprehensive way, not excluded or ignored to make research simpler.

WOMEN'S HEALTH RESEARCH

More than ten years ago [in 1990], my colleagues in the House and took action. Women were not being included in research trials at NIH. A study on heart disease risk factors was conducted on 13,000 men—and not one woman. So we went out to NIH to get a plan and a timetable to include women in research protocols. When we pulled up to the curb at the front door of NIH, they knew we were here, they knew we were serious. They knew we were going to have a Seneca Falls on NIH if necessary.

One month later, I worked with Ted Kennedy, Tom Harkin, and the women of the House. There was an Office of Research on Women's Health at NIH. I worked with these same Galahads and others in Congress to make sure that the women's health office would stay at NIH by putting it into law.

This Office has made a real difference in how women are treated for certain illnesses. We now know that men and women often have different symptoms before a heart attack. Women's symptoms are more subtle, like nausea and back pain. Knowing these symptoms means women can get to the hospital sooner and can be treated earlier. That's turning women's health research into life-saving information.

WOMEN'S HEALTH OFFICE ACT

Women's Health Offices—like the one at NIH—mean that women's health needs are always at the table, focusing on real, life-saving results. These offices make sure women are included in clinical drug trials, reach out to low-income and minority women to make sure they are getting vaccines and cancer screenings and work with health care providers to put research on women's health into practice.

I have introduced the Women's Health Office Act with my colleague, Senator Olympia Snowe to make sure that Women's Health Offices at HHS, CDC, FDA, Agency for Healthcare Research and Quality, and the Health Resources and Services Administration, are there for the women who count on them and can't be abolished without the consent of Congress.

Nearly every Federal agency within the Department of Health and Human Services has an office or officer of women's health, but today these offices and the important work they do can be abolished with the stroke of a pen, without the consent of Congress. Going back to the days when women's health needs were ignored by eliminating the offices we fought to put in place over the last 10 years is an unacceptable step backwards.

The Women's Health Office Act will ensure that we keep moving forward by making these offices permanent and providing a strong framework for these offices to give women's health a clear, consistent voice at the Department.

CLOSING

I look forward to hearing from the Society for Women's Health Research on the Women's Health Office Act legislation and from other witnesses to talk about Safe Motherhood, cardiovascular disease, and domestic violence. I look forward to working with my colleagues to get a women's health bill signed into law this year.

Senator MIKULSKI. Dr. Marks, we welcome you with your excellent background, from the Center for Chronic Disease Prevention and Health Promotion at CDC. CDC has been a very good friend to the women of America.

Please proceed, and I am going to ask you to summarize as well, Dr. Marks, and ask unanimous consent that your full statement be included the record.

Dr. MARKS. Thank you very much.

I am pleased to be here, and I do want to thank you, Senator, and the other members of the committee for their long history of support for CDC's work to improve the health of women.

I will summarize my remarks.

First, it is well-established that chronic diseases cause most of the deaths among women in this country, so this hearing really could not come at a more opportune time.

Probably foremost among the CDC programs that deal mostly with the health of women is the Breast and Cervical Cancer Early Detection Program, which has now supported over 3 million screening exams for women who have no health insurance and has detected over 10,000 cancers.

We have seen large increases in the screening rates for poor and near-poor women, and we have begun to see, as you have heard, the mortality from breast cancer decline as treatment for cancer detected early has become increasingly effective. We hope to see the number of deaths, now about 50,000 a year, decline over time.

Heart disease and stroke are often thought of as diseases that are more common in men, and actually, they kill more women than men—nearly 500,000 a year. This led us to develop the Wisewoman demonstration program.

In the Breast and Cervical Cancer Program, they identify women who really have no connection to health care in selected States, and the Wisewoman program works with those women to determine if they have high blood pressure, high cholesterol, or other risk factors for heart disease, and to see that they get screening, lifestyle——

Senator MIKULSKI. Diabetes is included in that as well, isn't it?

Dr. MARKS [continuing]. Increasingly, diabetes, and in some States, osteoporosis as well—so that they can get treatment if necessary and screening and lifestyle interventions.

We have been excited at how the States have responded to this. We know that there are still challenges with it. But it is an important program because it does help women who have no other source

of health insurance to get treatment for the other conditions, not just the screening for breast and cervical cancer.

There are unique health risks that women are subject to in pregnancy and delivery, and they have shown little or no progress in the last two decades in deaths and serious complications. We sponsored a Summit on Safe Motherhood last year to bring together researchers, clinicians, and policymakers to raise the visibility and concern about this lack of progress.

The concern has increased because there are large disparities between majority and minority populations. African American women are three to four times as likely to die as white women during pregnancy.

We have begun a series of research projects and collaborations with State health departments to better understand the causes and the severe complications and to begin to provide them with support for getting local data and looking at emerging issues like postpartum depression.

Dr. Slater has already commented on the twin epidemics of obesity and diabetes. They are more common in women than they have been in the past. They are increasing rapidly and are increasing even more rapidly among minority women.

Just this past year, with partners like the American Diabetes Association, the State and Territorial Health Officers and others, we launched a new initiative for diabetes and women's health to focus attention on the large and unique impact that diabetes has in women.

Some of the State programs, New York being among those, have developed networks in rural areas to reduce amputations and to improve the quality of care for people with diabetes. In the New York project that is based out of Syracuse, they have seen a reduction of about one-quarter to one-third in amputations and hospitalizations among people with diabetes.

I can only mention a few of the areas where CDC is working with States and communities to develop these responses, but make no mistake that it is important that we deal with the conditions of the chronic illnesses that are either unique to women, more common in women, or are major causes of death, disability, and suffering among women in the U.S.

Effective measures exist today to prevent much of the chronic disease burden and curtail the consequences. Another generation of women should not suffer unnecessarily or die when there is so much that we already know that we are not getting out. We at CDC and others in the Department are working to minimize this delay.

Thank you for the opportunity to testify, and I will be happy to answer questions, as I am sure Dr. Slater will as well.

[The prepared statement of Dr. Marks follows:]

PREPARED STATEMENT OF JAMES S. MARKS, M.D., M.P.H.

INTRODUCTION

I am Dr. James Marks, Director of the Centers for Disease Control and Prevention's National Center for Chronic Disease Prevention and Health Promotion. I am pleased to be here today to participate in this important public health hearing on women's health.

BURDEN BACKGROUND

As this committee knows, the burden placed on our society by chronic diseases is enormous. Heart disease, stroke, diabetes, and cancer combine to cause 63 percent of the deaths or 1.5 million Americans in the United States each year. In addition, more than ten percent or 25 million Americans experience major limitations in daily living due to a chronic disease or condition. The combination of chronic disease death and disability accounts for roughly 70 percent of the $1.2 trillion spent on health care each year in the United States. The increasing burden these diseases and risk factors impose on the health of women in our society is also problematic. Let me be more specific, while heart disease and stroke are commonly viewed as diseases that primarily affect men, more than half of all people who die of heart disease and stroke are women. Lung cancer has now surpassed breast cancer as the leading cause of cancer deaths among women and a woman who smokes has over four times the risk of dying from lung cancer as she does from breast cancer. Despite that fact, 22 million adult women currently smoke and over two million high school girls smoked during the past month. Diabetes is now the sixth leading cause of death in the general population, and diabetes disproportionately affects racial and ethnic minority populations, the elderly, and women. More women than men have diabetes and subgroups of women suffer disproportionately from this disease. For example, between 1990–2000, diabetes rates in women aged 30–39 years increased 50 percent. In addition, women with gestational diabetes, a unique and serious condition in women, have up to a 63 percent risk of developing type 2 diabetes later in life.

Unfortunately many of these cases are undiagnosed and these women with diabetes are at a greater risk—two to four times—for cardiovascular disease and stroke. Physical activity is a key factor in reducing a woman's risk for cardiovascular disease and stroke and yet 75 percent of adults are not physically active. This figure is even more striking when you consider more women than men are physically inactive. Further complicating this problem is the growing obesity epidemic in our society and among women with an estimated 50 percent of U.S. women older than 20 overweight.

The onset of chronic diseases and conditions are not the only preventable health risks facing American women today.

Maternal mortality remains an important public health issue in the 21st century. Over the last 20 years trends in maternal morbidity and mortality have not improved and, even more alarming, the racial and ethnic disparities associated with maternal death in the United States have not decreased. About one in four women, or one million women annually will have serious complications during labor. For every 100,000 deliveries in the United States, approximately 20 women will die from pregnancy and its complications. Racial and ethnic disparities persisted among black, Native American, Hispanic and Asian immigrants, or older women who were more likely to die (300 to 400 percent) than their white or younger counterparts. The *Healthy People 2010* goal is to reduce the maternal mortality ratio to 3.3 maternal deaths per 100,000 live births and eliminate racial disparities in health outcomes. With the current ratio at 9.9 per 100,000 live births, we have much work to do to reach this goal and prevent needless maternal deaths. In addition, we are also striving to prevent the even more common pregnancy-related complications such as hemorrhage, ectopic (tubal) pregnancies, pregnancy-induced hypertension, infection, and postpartum depression. For every 100 pregnant women who go to the hospital for delivery, 20 are hospitalized before delivery for complications. For every 100 women who deliver an infant, 31 have a complication during labor and delivery. Again, Healthy People 2010 sets a reasonable goal of no more than 24 women with complications per 100 deliveries and we have a long way to meet this goal.

CDC has accomplished many noteworthy improvements in the area of women's health, particularly in the areas of breast and cervical cancer and in diabetes with effective prevention strategies designed to reduce the burden of risk factors of these diseases.

PREVENTION RESEARCH

Prevention research represents the scientific foundation upon which CDC relies, to engage in our mission as the nation's prevention agency. Prevention research identifies the risk factors for disease, designs and tests interventions to prevent them, and develops and evaluates systems to deliver the interventions to the populations who need them. Prevention research serves as a transition vehicle that carries the basic biomedical research from the lab bench to the public health trench where the preventive services can be effectively delivered and sustained over time.

Prevention research results form the backbone of public health policies, standards and guidelines, best practices, and evaluation of their impact on health outcomes.

CDC's prevention research activities include two complementary areas: the Prevention Research Centers and the Extramural Prevention Research Program. CDC's Prevention Research Centers are a national network of academic, public health, and community partners that collaborate to conduct scientific research and put the results into everyday practice. The first three centers were funded in 1986, and over 15 years later, the program is comprised of 26 academic research centers in 24 States. Each center conducts at least one core research project with an underserved population that has a disproportionately large burden of death and disability, often due to adverse socioeconomic conditions. The centers work with diverse groups, such as women, adolescents, and the elderly and in geographically distinct areas, such as Harlem, Appalachia, and the U.S.-Mexico border.

The unique contribution comes from the close and long-standing relationships that develop between researchers at the academic institutions and the people they serve. Because of ties to surrounding communities, built through community advisory groups, researchers can develop and introduce prevention strategies desired by the communities. Moreover, by understanding community attitudes and beliefs and by making the most of community resources, researchers can simultaneously address multiple health risk factors. Further, academic affiliations often enable researchers to engage with communities in which government researchers traditionally might not have been welcomed. Prevention researchers also help develop community capacity to sustain healthy behaviors and activities after the researchers are gone.

In other CDC supported studies, investigators developed and pilot-tested materials appropriate for different socio-cultural groups. Researchers also have tested the effects of church-based interventions and health promotion strategies that incorporate spirituality. Some studies resulted in highly tangible benefits—such as walking trails that promote physical activity among men as well as women in a community. The contributions to women's health research also included more than 50 research instruments and assessment tools—such as measurement scales, surveys, and focus group guides—and more than 20 training curricula and instructional materials. The measurable improvements that occurred in the health of the women who participated in these studies also should not be overlooked or underestimated.

CDC's Prevention Research Centers at the University of Alabama at Birmingham (The Wilcox County Health Project) and the University of North Carolina at Chapel Hill (Health Works for Women) are two examples of this program in action. While death and disability from heart disease are higher for African Americans than whites, less is known about how to reduce heart disease risk factors among African Americans than for whites. In 1998, the University of Alabama's Center for Health Promotion started a demonstration project to reduce the risk for cancer and heart disease among African Americans living in three rural communities in Wilcox County, Alabama. About 70 percent of the county's residents are African American, and nearly half live below the poverty level. The intervention began by recruiting Community Health Advisors (CHAs), who were trained in leadership skills, community problem solving, and strategies for reducing risks for chronic diseases—in themselves, in their families, and among their neighbors. Nearly all of the more than 50 CHAs who graduated from the project's training were women. The CHAs conducted community wide health promotion activities as well as classes on nutrition, physical activity, and smoking cessation. Ongoing activities that hold promise of reducing disease risks include the creation of walking clubs and Farmer's Markets (to compensate for fresh fruits and vegetables not readily available at local grocery stores), the distribution of anti-smoking materials and heart healthy cookbooks, and the construction of a walking trail. While the participants benefit from this research, the researchers collect valuable data about how to design cost-effective interventions that can be articulated and widely disseminated to women and men in comparable communities. Only through close community participation, trust, and mutual benefits is such knowledge gained through the Prevention Research Centers.

The University of North Carolina's Center for Health Promotion and Disease Prevention conducts some prevention research in the workplace, an environment that serves as a creative partner for research and dissemination. Health Works for Women focuses on women working in textile manufacturing in a rural section of North Carolina. Many of the women who live and work in the area are at a higher than average risk of developing chronic diseases such as heart disease, cancer, or diabetes. The program, which is unique in its focus on blue-collar women, is increasing physical activity, improving nutrition, and decreasing smoking, and increasing screening for breast and cervical cancer among participants. As in Alabama, women are recruited as lay health advisors and trained to educate co-workers about healthy ways of living. The women engaged in the study have credited the program with

having given them guidelines and group support. Researchers codify the elements that contribute to the program's success and replicate them at other sites. They also note the extra benefit from this type of intervention: the reach beyond the worksite, into the participants' homes, churches, and communities. Testing and disseminating approaches such as these does not require a research laboratory but partnership and shared values.

In discussing women's health, it is important to recognize that our prevention researchers also are addressing the passage into womanhood, which does not begin at one given age. Several centers, including the Johns Hopkins University's (JHU) Center for Adolescent Health Promotion and Disease Prevention and the University of Minnesota's National Teen Pregnancy Prevention Research Center, are promoting healthy development among young women. At JHU, researchers are studying relationships between health behaviors and school performance of middle school youths. At Minnesota, researchers are conducting peer health education training to evaluate its effectiveness on preventing pregnancy among 13 to 17 year olds at high risk for pregnancy.

The Prevention Research Centers have the flexibility—as well as the requirement—to draw on multidisciplinary faculty with expertise in public health, medicine, psychology, nursing, social work, education, and business. The knowledge from all these disciplines must converge so that the research and practice communities can understand and successfully address the inherent complexity of chronic health problems. The Prevention Research Centers long-term alliances with State and local health departments, other health care delivery programs, and community and voluntary organizations have enabled the translation of research findings into practice.

Over many years now, prevention research in general and CDC's Prevention Research Centers in particular have demonstrated remarkable contributions to enhancing women's health, contributions crucial to sustain.

In 1999, CDC established the Extramural Prevention Research Initiative to begin to unlock the extraordinary benefits of prevention research. A $15 million appropriation launched this initiative and provided support for investigators in academic settings with linkages to communities. The driving principles of the initiative are to:

- Support population-based research priorities identified by CDC and external experts in prevention science and public health practice;
- Incorporate community goals and perspectives in research design and conduct;
- Support investigator-initiated extramural research;
- Use external peer review to identify the highest quality research; and
- Ensure translation of research findings into public health tools and best practices.

The initiative is now in its second funding cycle and anticipates about 30 new projects will be funded in fiscal year 2002. What is unique about this second funding cycle is that practitioners, policymakers, and community members are being invited to participate with researchers in identifying important research questions and in interpreting and applying the research findings so that the research will have greater relevance and usefulness for individual communities. The program announcement was published on February 21, 2002 and can be accessed on CDC's website at the following address: http://www.phppo.cdc.gov/eprp/PRPA02003.asp.

While CDC has dedicated significant resources to the prevention research, the value of this research lies in the ability of the public health community to translate this research into effective public health practice. Without this translation the potential savings in lives and dollars will never be realized and prevention research will fall into the abyss of "research for research's sake." At CDC, we are dedicated to developing public health programs that are built in the foundation on prevention research and dedicated to saving lives and reducing the economic burden of health care on our society. Prevention research can play a vital role in developing prevention interventions, improving the delivery of prevention services and improving the quality of health care. The following programs will describe how prevention research has and will provide the necessary foundation for current and future public health initiatives.

DEVELOPING PREVENTION INTERVENTIONS THROUGH RESEARCH

Safe Motherhood is a universal issue that affects women, men, children, the workplace, health systems, and society as a whole. It encompasses women's health before, during, and after pregnancy, and is grounded in the understanding that healthy pregnancies can occur only in the context of general good health for women. Safe motherhood addresses the physical, mental, cultural, and socioeconomic aspects of women's lives. In the fall of 2001, CDC and its partners held the National Summit on Safe Motherhood, which brought together a broad spectrum of researchers,

clinicians, program experts, policymakers, and advocates to address the complex challenges of safe motherhood. This summit established four major goals that need to be considered to address the health risks associated with motherhood in this society. These goals include: reducing the rates of maternal mortality and complications; eliminating disparities in maternal health outcomes; collecting good data on the frequency of these complications and good research to find out why these problems occur; and, utilizing these research findings and moving to evidence-based prevention interventions. I would like to take this opportunity to review the challenges associated with these goals and the current CDC efforts to address these challenges.

Maternal mortality, which is about three deaths per day, is not decreasing according to evidence compiled by CDC's National Center for Health Statistics. This rate is unchanged for the past 20 years. In addition, CDC's Pregnancy Mortality Surveillance System (PMSS), a cooperative effort with State health departments, provides evidence that the risk of maternal death is generally underestimated by relying on death certificate information alone. Through PMSS, CDC collects birth and death certificates for pregnancy-related deaths and compiles all available information in PMSS. This information can be used to monitor the number of pregnancy-related deaths and to analyze factors associated with them. For pregnancy complications, we have estimated their magnitude from data based on numbers of hospitalizations during pregnancy; however, due to changes in prenatal medical management, today this information is unable to capture the complexity and spectrum of these complications.

The elimination of population disparities is key to reducing the rates of complications and mortality. PMSS has also given us information about disparities. A woman's race, ethnicity, and age affect her risk of pregnancy-related health consequences. These disparities are most evident for pregnancy-related deaths. In addition to racial and ethnic disparities, the risk of death also differs by age. Women aged 35–39 are twice as likely to have a pregnancy-related death compared with women age 20–24, and the risk is even greater for women over 40. Since pregnancies among women in their late 30s have increased by 74 percent, and among women over 40 by 38 percent in the last quarter of a century, the number of women exposed to this increased risk is rising. CDC collaborates with private and public partners across the United States to address the disparities issues. These collaborations include:

- A study with University of Illinois at Chicago to define severe complications during pregnancy and risk factors for these conditions;
- A study with Columbia University to investigate illness during pregnancy from infectious causes;
- A research effort with the State of Massachusetts to determine the reasons some women who have had a cesarean section experience uterine rupture during a vaginal birth later in life;
- A collaboration with the Massachusetts Department of Health to develop the fast comprehensive data set for a State population of births conceived using assisted reproductive technology;
- A publication with professional and public health organizations, and other Federal agencies to guide States in the conduct of maternal mortality reviews, titled "Strategies to Reduce Pregnancy-Related Deaths. From Identification and Review to Action;"
- A project with Wake Forest University to investigate risks for maternal mortality and the reasons risks differ according to race;
- A collaboration with the Health Resources and Services Administration through the Maternal and Child Health Epidemiology Program (MCHEP) to provide technical assistance to States to enhance their capacity to gather and use data. Through MCHEP, epidemiologists specializing in maternal and child health serve eleven States (California, Georgia, Hawaii, Mississippi, Michigan, Louisiana, Ohio, Maryland, Colorado, Maine, and Kentucky) and two Indian Health Agencies (Northwest Portland Indian Health Board and the Indian Health Service regional office in Albuquerque);
- A collaboration with States on the Pregnancy Risk Assessment Monitoring System (PRAMS) to monitor risk factors for adverse pregnancy outcomes; and,
- A National STD-related Infertility Prevention Project which provides routine screening for chlamydia of at-risk women at family planning clinics and in managed care settings.

Despite these efforts, neither complications nor disparities among American women can be fully addressed due to inadequate data sources. There is no standardized method to define conditions that are considered pregnancy-related illness. Even pregnancy-related deaths, events that generate vital records, are undercounted and sometimes improperly classified. The recent shift to management of complications

in an outpatient setting further hinders our ability to accurately measure these conditions. Therefore, estimating the burden of these conditions on a State and national level is difficult. CDC is planning a workshop to address problems associated with defining and measuring maternal morbidity, and to investigate the use of previously unexplored data sources. Collecting accurate data is essential to drive a meaningful research agenda.

Finally, we learned from the National Summit on Safe Motherhood that local, evidence-based public health prevention will occur only when we have improved maternal health data and enhanced research in maternal health. As we learn more about maternal complications and their risk factors, researchers at national and State levels, universities, and in the private sector will have a rational basis to design interventions and demonstration projects. We have made much progress but there is still much to do to reduce maternal deaths and complications and eliminate disparities.

IMPROVING PREVENTION SERVICES

One of CDC's most successful prevention interventions has been the National Breast and Cervical Cancer Early Detection program. Recognizing the value of appropriate cancer screening, Congress passed the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101–354) which enables CDC's National Breast and Cervical Cancer Early Detection Program to provide critical breast and cervical cancer screening services to underserved women, including older women, women with low incomes, and women of racial and ethnic minorities. As the flagship of CDC's cancer control efforts, this program has saved lives, and raised the consciousness of Americans everywhere about the importance of screening and early detection in preventing deaths from cancer.

Through September of 2000, more than 3.0 million screening tests have been provided to over 1.8 million women. That number includes 1.6 million Pap tests and 1.4 million mammograms. Almost half of these screenings were to minority women, who have traditionally had less access to these services. Over 9,500 women have been diagnosed with breast cancer, more than 40,000 women were diagnosed with precancerous cervical lesions, and 715 women had invasive cervical cancer.

The program's success is due in part, to a large network of professionals, coalitions and national organizations dedicated to the early detection of breast and cervical cancer. This success has been reflected in a broader effort to promote screening to the general public. As a result, the percentage of women aged 40 and older who reported ever having a mammogram increased from 64 percent in 1989 to 85 percent in 1997, and the percentage of women who reported receiving a mammogram within the previous two years increased from 54 percent in 1989 to 71 percent in 1997. Disparity rates for mammography utilization among most minority groups have either been eliminated or reduced substantially, and overall, there has also been a recent decline in the rate of breast cancer mortality among all women. While there remains much to be done, our most recent mortality data shows that 18.8 women per 100,000 die of breast cancer. This achieves our Healthy People 2010 goal of reducing mortality from 23 women per 100,000 to 20.6 women per 100,000.

While we acknowledged the importance of preventing or curing all cancers, let me be clear: we know today how to prevent up to 30 percent of all deaths from breast cancer. It's not a new scientific breakthrough; it's mammography—this technology and the recommendation for regular screening has been around since the late 70's. Mammography is currently the single most effective method for diagnosing breast cancer early. The longer breast cancer remains undetected and untreated, the greater the likelihood it will spread. The five-year survival rate drops from 97 percent when breast cancer is diagnosed at the local stage to 21 percent when it is detected after having spread. We know these figures are not lost on this committee. In fact, exemplifying Congress's commitment to saving lives was demonstrated in October 2000 with the signing of the Breast and Cervical Cancer Treatment Act of 2000 into law. This law gives States the option of providing full Medicaid benefits to uninsured women who are screened with breast or cervical cancer by the CDC screening program and found to need treatment. We commend Congress, this committee, the National Breast Cancer Coalition, and the American Cancer Society for this unprecedented legislation. To date, 37 cover the new Medicaid option.

What's our vision for the future of the breast and cervical cancer early detection program? Quite simply, we want no woman to die because she lacked knowledge, access or finances for screening services. The science is there but the challenge lies in identifying, educating and motivating women who have rarely or never been screened for cancer. This is challenging and labor intensive work that relies on CDC's outreach efforts to bring the science of screening into the lives of the women

who need it the most—those most at risk for cancers that are preventable and survivable.

IMPROVING QUALITY OF CARE

Today, through the diligence of science and research, and the constancy of surveillance, we know a lot about diabetes—and that knowledge base is expanding rapidly. Through significant advances in diabetes research, we know that improving nutrition, increasing physical activity, controlling blood glucose levels and improving access to proper medical treatment can delay or stop the onset and progression of diabetes complications. Applying our knowledge could prevent much of the suffering caused by the devastating complications from diabetes. And now, there is strong evidence that prevention or delay of the onset of diabetes is possible if we can develop effective strategies and interventions targeting weight loss, increased physical activity, and improved nutrition.

As part of a comprehensive effort to improve women's health, CDC launched a new National Initiative for Diabetes and Women's Health to focus national attention on the unique impact diabetes has on women's health and how it can affect future generations. Cosponsors in this endeavor include the American Diabetes Association (ADA), the American Public Health Association (APHA), and the Association of State and Territorial Health Officials (ASTHO). This initiative consists of three phases: the preparation and publication of *Diabetes & Women's Health Across the Life Stages: A Public Health Perspective*, a monograph that examined the issues that make diabetes a serious public health problem for women (available at http://www/cdc/gov/od/oc/media/r010509.htm or http://wwwv/cdc/gov/diabetes); the development of *Proposed Recommendations for Public Health Action* focused on the strategies, policies, surveillance, and research for improving the lives of women diagnosed with or at risk for diabetes (completed in November 2001); and finally, the preparation of the *National Action Plan for Diabetes and Women's Health—A Public Health Initiative* that will outline how the recommendations should be implemented, by whom, and in what time frame during a national diabetes summit scheduled for August 2002.

This year marks the 25th anniversary of CDC's diabetes program—a program established by Congress to translate diabetes research into public health practice. The program began in 1977 with an appropriation of $1.5 million to fund 10 States and 10 FTE's. Today, the diabetes program funds all 50 States, the District of Columbia and eight U.S. territories to implement diabetes prevention and control programs. Since its inception, the goal of CDC's diabetes program has been to reduce the preventable burden of diabetes by translating diabetes research into public health practice. CDC's diabetes program accomplishes its mission by developing surveillance systems for use at State and local levels, especially for monitoring the diabetes burden among certain racial and ethnic populations; developing and implementing innovative interventions and prevention strategies for eliminating racial and ethnic health disparities; and by informing and educating people with diabetes, providers and policy makers about the seriousness of diabetes and the importance of preventing diabetes related complications. The program has built a national network of State-based diabetes control programs, and it has a strong track record and impressive outcome data.

The diabetes program to date has focused on tertiary and secondary prevention. The program has evolved with advances in diabetes research science; and since 1994, moved away from providing direct care for a few to influencing improved quality of care on a large scale (i.e. health systems) to help all people with diabetes. This approach requires strong partnerships at the national and State levels and accountability based on the progress achieved in meeting explicit and concrete national objectives.

CDC relies heavily upon the States to provide the essential framework for delivering population-based diabetes prevention and control programs. The programs are required to work with partners to improve the quality of, and increase access to diabetes care, to involve communities in improving diabetes control, to inform and educate health professionals and people with diabetes about the disease, and to identify high risk populations, including American Indians. These State-based diabetes control programs are the primary implementation arm of CDC's National Diabetes Program.

The accomplishments of the State-based diabetes control programs reflect several process and intermediate outcome measures. One example of these measures is glucose control, which is measured by the blood test—A1C (the blood glucose test all persons with diabetes should have about twice a year which provides a long-term measure of glucose in the blood). A1C levels predict future diabetes complications,

and in general, the lower the A1C measurement, the better. Obtaining this test is the first step; reducing the A1C level is a necessary second step. Both performance indicators are now used within the HEDIS system. Other indicators of program performance include prevention behaviors, e.g. examining eyes or feet; and some data on more distal outcomes, such as lower extremity amputations.

To illustrate the depth and breadth of the impact of the diabetes control programs, I will share the accomplishments of four Diabetes Control Programs (DCPs)—Michigan, New York, Project DIRECT in NC, and Minnesota. These programs represent efforts in rural, urban, community and managed care settings. They focus on different populations and approaches, but common elements cut across them—funding, technical guidance, effort, time and commitment to evaluation. These programs represent a small number of DCPs, currently 16, that receive expanded funding to provide statewide diabetes control activities.

Michigan

The six regional Diabetes Outreach Networks are the cornerstone of the Michigan DCP. These networks, especially in rural areas, create partnerships among hundreds of community agencies to strengthen diabetes prevention, detection, and treatment throughout the State. The first network UPDON was established in the rural Upper Peninsula. It was our first indication that improved distal outcomes could be examined. After its first 5 years, UPDON showed promising decreases in hospitalizations and lower extremity amputations, in the 25 percent range. More recent data from 1997 show continued, impressive improvement in key preventive care practices, including A1C testing, foot exams, eye exams, flu and pneumococcal vaccinations, and lipid profiles.

The remaining Diabetes Outreach Networks of MI have expanded this model, and there are now more than 26,000 persons with diabetes in the Quality Care Improvement Project. The the rate of A1C testing has doubled in about 4 years. Getting the right test at the right time is the first step in preventing diabetes complications. The next step will be to improve A1C levels. Because of such compelling data, the State of Michigan itself now contributes more money to diabetes prevention and control than CDC—just over $3 million per year, in essence a 4 to 1 match with CDC's funds.

New York

The New York State Diabetes Prevention and Control Program adopted and modified the Michigan model for more urban settings by establishing regional community coalitions and academic Centers of Excellence to improve the quality of diabetes preventive care and access to care. Examples of the interventions include complex programs to get community groups and clinicians to achieve consensus on what should be done, and then to identify specific activities to convert this consensus into reality, e.g. mailing reminders about pending clinic visits; or having people with diabetes take their shoes and socks off in the exam rooms to help stem the rate of amputation.

From 1996 to 1999, hospitalization rates for persons with diabetes decreased by 30 percent and lower extremity amputation rates decreased by 36 percent. In addition, rates of annual A1C testing more than quadrupled, increasing from about 15 percent in 1994 to 77 percent in 1999. The public health interventions that underlie these impressive gains do not rely on new molecular or genetic science. Rather, they represent thoughtful, cooperative, and sustained efforts to take existing science, and then decide how to change the actual delivery of diabetes preventive care.

Minnesota

Project IDEAL, Improving Diabetes Care through Empowerment, Active Collaboration, and Leadership, is an important DCP project which targets a managed care setting. The Minnesota Health Department and HealthPartners developed project IDEAL, a large managed care organization. IDEAL is a system-wide approach that enables clinics to re-engineer delivery of chronic disease care by changing the structure and process of diabetes care, through a variant of case management.

The IDEAL project demonstrates that it does take time to achieve, document, and publish concrete results. For IDEAL, teams were formed in 1994, baseline data were collected from 1995 to 1996, the intervention was conducted in 1997–98, and the project is now in the dissemination phase.

During the pilot, substantial increases were observed in annual eye exams, foot exams, and microalbumin testing, and these findings were replicated in the intervention. In addition, average A1C values decreased during the trial from 9.2 percent at baseline to 7.7 percent in the second year, and this contribution effect has been duplicated in cross-sectional data for the entire medical group, with reductions from 8.6 percent in 1994 to 7.4 percent in 1999. For reference, a one percent decrease

in A1C is associated with a 40 percent decrease in microvascular complications. Another important note: these levels of A1C—in the low 7's—are comparable to those obtained with intensive treatment in the Diabetes Control and Complications Trial and the U.K. Prospective Diabetes Study, two landmark clinical trials with relatively unlimited resources.

Similarly, average LDL-cholesterol concentrations decreased from 132 to 116 mg/dL from 1995 to 1999. Other impacts of this strong collaboration include a higher priority for diabetes care in GroupHealth, application of the IDEAL methodology to address asthma, heart disease, hypertension, and other conditions. In addition, Stratis Health, the Minnesota Medicare PRO, is implementing IDEAL with its clinics.

This strong collaboration has resulted in a higher priority for diabetes in managed care, and application of the IDEAL methodology to address heart disease, hypertension, and asthma.

These examples, from diverse settings—rural, urban, community and managed care—demonstrate that DCP's can make a real difference in improving the quality of diabetes care. These interventions provide an array of proven, effective programs for other States and communities. With adequate funding, guidance, and time, they clearly work. They achieve outcomes comparable to those in the most rigorous clinical research studies. If the approaches are further disseminated, the public health impact will be substantial.

Diabetes is a prototypical chronic disease. It is serious, common, costly, and complex. It imposes an enormous and growing public health and societal burden. For women, the impact of diabetes is unique and profound. The quality of care for many people with diabetes, while improving, still remains poor. Through translation research, State DCP's and their collaborators have developed a potent and growing array of science-based interventions to reduce the burden of diabetes, through secondary and tertiary prevention.

The compelling new evidence for primary prevention of diabetes indicates that investment in translation research for primary prevention must now complement ongoing work to improve the quality of care. The States and CDC are beginning to wrestle with this important and exciting challenge.

BUILDING ON OUR SUCCESSES

Finally, let me describe an ongoing effort to utilize the success of one prevention program as a springboard for testing the efficacy of another prevention program. As this committee knows, Congress established CDC's Well Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) program in 1993 as a pilot preventative services program that utilized the existing breast and cervical cancer-screening program as an opportunity to offer low-income women additional screening services.

CDC currently supports 12 WISEWOMAN projects in 11 States. These projects utilize the existing State-based breast and cervical cancer screening system to offer women heart disease screenings, chronic disease risk factor screening, dietary and physical activity interventions, and medical referrals when appropriate. Since the programs inception, approximately 10,000 low income and uninsured women have been screened for heart disease risk factors. Between 50 and 75 percent of the women screened at each site were found to have either high blood pressure or high cholesterol. Women screened for these risk factors were provided intensive individual counseling, group counseling, and lifestyle classes aimed at improving nutrition and physical activities levels.

CDC is currently evaluating the effectiveness of these interventions. The goal of this preventive research effort is to determine interventions that most effectively prevent or delay cardiovascular and other chronic diseases among these at-risk women. CDC is currently in the process of evaluating the effectiveness of these programs, in part, through collaboration with the Prevention Research Centers and anticipates that the program will continue to test prevention interventions and disseminate the successful strategies as they are identified through the program. Once these interventions are identified, CDC will work with States to implement the interventions where appropriate.

CONCLUSION

Prevention research provides us with the opportunity to link basic biomedical research to the world of public health. The biomedical breakthroughs of today and tomorrow provides the fuel to ignite public health interventions that will save lives and reduce spiraling economic costs. The ideal of a cure for these diseases is something we should always strive for no matter the circumstances. However, until these

cures are discovered, we need to use the basic research as effectively as possible and save lives through prevention. We should always strive for prevention even after cures are found, since there are often side effects to disease and to medication.

Let me share a story about one life saved by the prevention research I have described here today. It's Beth's story. Beth's husband David lost his job after 28 years. Before David lost his job, Beth made sure to get a mammogram every year. This time, Beth waited five years before she was checked. She might never have had another one if she hadn't found out about Ladies First, the Vermont breast and cervical cancer-screening program. When Beth went in for her free mammogram, it was none too soon. Beth's mammogram showed a lesion that turned out to be cancer. The good news is that doctors caught Beth's cancer early enough to treat it successfully. With other help from Ladies First, the cancer treatment was not a financial burden for Beth or her husband. Beth credits Ladies First with saving her life.

There are many Beths out there, and we love to hear their stories. But what concerns us most are the Beths we don't hear about—the women who do not get regular screening because they don't know about the programs or the programs do not exist yet. We want to identify as many of these women as possible and catch their diseases early so that we can make the science work for those who need it the most and those who need it now.

That concludes my testimony. I would be happy to answer questions from the committee.

Senator MIKULSKI. Thank you for that excellent testimony.

Senator Clinton, do you want to go first?

Senator CLINTON. I want to thank both of you, and I think that your testimony is very helpful in raising the visibility of some of the challenges that we confront, and I believe that adult-onset, Type II diabetes has not been given the attention that it needs. I was struck by Dr. Slater's statement that it is the fifth leading cause of death among women. I can guarantee you that not many of us knew that before your testimony.

Dr. Slater, in your written testimony, you also talked about the role of violence in the lives of women, and that too is an area where we need to look at it as a health issue, not just as a law enforcement issue and a cultural concern.

Could you give us some information about what you are doing to address domestic violence and the health impacts?

Dr. SLATER. Yes, a pleasure, Senator. Again because of the limited time, I truncated the presentation.

I believe you are familiar with the Healthy People objectives for the year 2000 and again for the year 2010, which is a very important way of tracking our progress in terms of interventions in public health. Twenty-six of the Healthy People 2010 objectives relate in some way, shape or form to domestic violence, and this administration is very, very committed to this very important problem that you are aware of and that is a problem that again appears to disproportionately affect women. You are well aware of the statistics—one-third of women are murdered by individuals with whom they are quite familiar; roughly one million women per year report being stalked. So there is really great difficulty.

Health and Human Services has a Violence Against Women Steering Committee, as you know, That committee is chaired within my office and reports to the National Advisory Council on Violence Against Women, which is Presidentially-mandated and cochaired by the Attorney General and Secretary Thompson.

HRSA is responsible for a large number of domestic violence training programs. They have a 1–800 number—or perhaps it is a 1–888 number—ASK–HRSA, and one can log onto information regarding their many programs which are primarily focused on train-

ing the health care professionals who need to be more sophisticated in recognizing the signs of domestic violence. I think this is in some ways a reiteration of the issues of childhood abuse, and it was largely learned that by training the health care community, the interface, to recognize the signs and symptoms is how we will hopefully be able to make the first set of inroads.

Another topic that is sad to recognize for me, but one that we are also taking interest in, is the apparent increase in elder abuse. It is subtle. It is often missed. It is often unrecognized. But it is again something that unfortunately is rearing its ugly head and needs to be a concern of all of ours as we develop programs to deal with that.

There is an Intimate Partner Fact Sheet that CDC and Dr. Marks, my colleague, has on his website, which again is a very useful resource for the statistics, and again, we share your concern about that issue.

Senator CLINTON. Thank you.

Dr. Marks, I do not have a question. I just want to applaud you and CDC for what you are doing in prevention research. I think we have really woefully underfunded prevention research, and it is such a complicated area to get at behaviors and environmental impacts and the like, but I think it is key to devising successful public health strategies about how to deal with these various chronic disease challenges, and I really appreciate your leadership and look forward to working with you as you do more in the area of prevention research.

Dr. MARKS. Thank you very much.

Senator MIKULSKI. Thank you very much.

Dr. Frist?

Senator FRIST. Thank you, and I apologize to both of you. I had to speak at another hearing.

Let me just thank you, Madam Chairman, for calling this hearing today to examine the gaps which are so obvious in women's health care. I think we made huge progress in the last administration and are making real progress in this administration, and I want to applaud President Bush for all of his efforts in providing funds for research and prevention activities and treatment to improve the health of women throughout this country.

However, there are many, many additional steps that we can take and should take, and I appreciate your written testimony and look forward to the next panel to explore further what steps might be taken in an orderly, systematic, directed way, so we can close many of these gaps that exist.

Jumping right in, Dr. Marks, when we initially talked about S. 208, the Wisewoman Expansion Act, you had some reservations about the feasibility of the expansion, primarily related to the concern that the women who were being screened through the program would not be able to receive appropriate follow-up and medical services.

Do you still have those reservations, and if not, have things happened to change your mind?

Dr. MARKS. Thank you, Senator.

That is a good question, and I think that that is the most difficult part of the Wisewoman program. It basically screens women

who have been brought in through the Breast and Cervical Cancer Program, and a number of those women because they have no form of health insurance are not well-connected and have not been making anything resembling regular visits to health care provides. So some of them have very high elevations in blood pressure, cholesterol, and so on.

It was critical to us that we not just identify them but that we get them to treatment, so we require that of the States that apply. It is a demonstration program, and one of the things that we evaluate is whether they can do that.

Because these women have no insurance, the solutions are local. That is, sometimes they may have to contract with or get a local provider to be willing to see the women, to work with the neighborhood health centers that HRSA has.

The information that we are starting to get from the States suggests that they are able to do it, or at least do it in a majority of the cases, so I am starting to feel better about that, but we do have to recognize that it will be different in each place. We have to both capture the strategies that the early States have done to make those available for the new ones, but we also have to continue to monitor that it is effective and that we are getting them to them. As you know, conditions like blood pressure and cholesterol require lifetime treatment, so it is not something where we can be secure just because they got the first prescription filled, and that is all that is necessary.

Senator FRIST. Thank you. I very much appreciate your response. It is clear that we need to make sure that through our mutual discussion, we do everything possible to ensure that Wisewoman expansion is an efficient use of resources, so that ongoing input is very helpful to this committee.

Dr. Slater, in your written statement, you outlined that the Department of Health and Human Services will spend nearly $70 billion this year on women's health, most of those expenditures concentrated on the medical and public health services as well as research on diseases and conditions important specifically to the health of women.

Additionally, you describe in your testimony a myriad of activities which are ongoing at the Department. From your broad perspective, are there particular areas in which we need to refocus our efforts so that women receive the information, the prevention, and the care services they need?

Dr. SLATER. It is a wonderful question, Senator, and I wish we could spend hours discussing it. We all know that the ability to prevent a variety of diseases can be easy on the one hand—something like a baby aspirin—to something much more difficult when we tackle situations like diabetes and obesity which, as Senator Clinton mentioned before you arrived, involve issues of environment, genetics, behavior, a whole host of complex problems. You and I have struggled for years trying to get people to take a cholesterol-lowering drug or a blood pressure drug every day. Well, trying to alter one's diet and exercise on a daily basis is probably one order of magnitude more difficult.

One of the things that we would like to do is to take stock of all the wonderful expertise, some of which is contained in my briefing

books and in your briefing books, on the public health interventions across all agencies, across departments, in academe. There is a certain thread that some of these actually do work, some of them resonate. They may resonate for a variety of reasons, but what we would like to do at this point, in addition to all the wonderful creativity and invention that is going on, is take stock of those programs that actually do work and begin to develop the wherewithal to share those programs from one geography to the next.

I will share with you—hopefully, Jim and I will become a little bit of a tag team for you, because we have already begun to work a little bit—but Jim and I took a trip, actually, in November to a place in Michigan that had a diabetes intervention program. This is in your briefing book, and Jim describes this.

I was so impressed by the reduction in diabetes complications that were provided really on a shoestring simply by improved care. This was in the Michigan Upper Peninsula. Amputations were reduced by greater than 25 percent in a 2-year period of time. That is an enormous reduction in morbidity, human suffering, emotional suffering, disability, and the cost, obviously, to care for these people.

So that, actually, as a pilot in our department, we have developed a best practice initiative where we ask the successful program to just sum up what they did in two pages or so, and we are putting that on our website. We were just discussing this morning—we have a new one once a month, and we welcome anyone who wishes to submit these programs. We are going to try to figure out additional ways to share them, to clone them, and we might even be able to put more initiatives on here.

What I am saying in a nutshell is that we would like to take what we have learned, take stock of what we have learned, and then see if we cannot disseminate what we have learned in the best practice sense to improve and make a difference.

Senator FRIST. Thank you. I think that that focus and refocusing is something that is critically important as we go through to sharpen the use of the resources that we do have available and try to make the appropriate resources available.

Madam Chairman, I know we are going to have votes soon, so I know that we need to move along, but I want to take the liberty of saying that I first met Dr. Slater 25 years ago at around 5 o'clock in the morning when I was a bleary-eyed third-year medical student at Massachusetts General Hospital. In walked the chief resident, and her first words were, "Why aren't you working faster?" We used to have to draw blood in the morning from 20 patients, and she was a real workhorse. She said, "Soon-to-be Dr. Frist, get on that, work faster, be more efficient"—and it was all at 5 o'clock in the morning. And here we are 25 years later. That was all on the Bullfinch ward at Massachusetts General Hospital.

Senator MIKULSKI. Well, I think she is right—why don't we start working faster?

[Laughter.]

Senator FRIST. I know, I know. This is my one opportunity to tell her to use resources harder, more aggressively.

Senator MIKULSKI. I think that is great. I think that is right, and I am ready to draw a little blood on this committee, I will tell you that.

[Laughter.]

I think that sounds just right.

Senator FRIST. Thank you.

Senator MIKULSKI. Dr. Slater, we are looking forward to getting better acquainted with you, and because of another item before I walked in, I did not have the chance to really welcome you most warmly, as well as Dr. Marks, and to say that when it comes to working on the women's health initiative, we really work on a bipartisan basis. So I look forward to getting to know you better and the work better.

Dr. Marks, I also want to thank you personally as well as CDC for the way in which they implemented the breast and cervical cancer legislation. It is something that I helped initiate a number of years ago. We have continued to improve on it, and now, the way it is a gateway to other preventive screening under Dr. Frist and his excellent Wisewoman approach, I think is outstanding. So we want to thank you for what you have done.

Let me just go for a few quick comments and then to my own set of questions. First, just to step back, we have been working on the women's health agenda for a number of years, and it has focused primarily on, number one, getting women included in the research protocols—for a number of years, as you recall, they were not included—and also on improving research and focus on prevention and treatment of those things which were gender-specific to us, particularly things like breast and cervical cancer.

While we continue that focus, now, I think it is time that we also take a fresh look at those illnesses or conditions that we are really being adversely affected by. You have outlined them. The leading cause of women's cancer deaths is lung cancer, not breast cancer. On the issue of heart disease which has been raised also by our wonderful friend, Mrs. Irene Pollin, who has done a great deal in her preventive work—women are dying of heart disease, and women are treated differently. Men go into acute care and run off to Pritikin or Dean Ornish, and women go to Weight Watchers, which might be as much if not more effective. Somebody like me has been on the asparagus diet, told not to eat carbos, then eat carbos, and while you are at it, have more—whatever. So there is a lot of confusion.

But when it comes to us, we really need to take a look at what are the additional things affecting women and how they affect us perhaps differently, and also how, even within the treatment system, we are treated differently.

So for your ongoing thinking—and the testimony from both of you was outstanding, and we hated to have you condense it—but we really welcome you to think anew about this. Many of us have a variety of legislation pending—Wisewoman, etc.—but one that I have, and I just wonder if it would help—you see, the whole idea when we established the Office of Research on Women's Health at NIH was that it would work across all the Institutes and would not be a segregated issue, when we look at CDC, when we look at the variety of programs at HHS.

Senator Snowe and I are considering permanantly establishing Offices of Women's Health at FDA and other HHS agencies—you have one at CDC, Dr. Marks, and I am going to ask you for your observations on that—perhaps a permanent one-stop shop at HHS, Dr. Slater—so that again, across the spectrum of illnesses and diseases, or where we have conditions but they are treated like a disease, a la menopause—which is a condition, not a disease, but it requires treatment and management—I wonder what you think about the idea of having Offices of Women's Health in law to be coordinating and to think across condition or disease lines.

Dr. Marks, could you tell us what the Office of Women's Health has meant at CDC, if you are prepared to comment; and Dr. Slater, what do you think about that?

Dr. SLATER. Sure. Jim, do you want to go first?

Dr. MARKS. Thank you.

Ms. Yvonne Green, who directs the Office of Women's Health at CDC, is here, and you should know that it has been a very useful office at CDC. I am sure it reflects the importance of the number of issues we have to deal with.

It is important to link across them, and I can name several areas—for example, in the area of reproductive health, there are issues related to infection, there are issues related to quality of care, there are issues related to some of the chronic diseases that need to be addressed, and Yvonne's office in fact does that for us and helps to make those bridges possible.

Yvonne, would you comment?

Senator MIKULSKI. Would you introduce the director?

Dr. MARKS. This is Ms. Yvonne Green. Yvonne is director of the Office of Women's Health at CDC. She is a nurse-midwife by training.

Senator MIKULSKI. Do you have any response to my question?

Ms. GREEN. Our office serves a role through advocacy, communication, and helping to promote women's health in a variety of ways, including funding research through the different centers, institutes, and offices at CDC.

So we promote women's health; we work both internally and externally to coordinate and to form partnerships and other endeavors to promote women's health.

Senator MIKULSKI. Excellent. That is exactly what we wanted to do. Excellent.

Dr. Slater?

Dr. SLATER. Senator, I will take this opportunity—this is my first appearance before the HELP Committee—to tell you that I am so impressed by your particular interventions in women's health over the course of your career on this committee. Your track record really speaks for itself.

The issue of creating special offices or having groups nonlegislatively dedicated to women's health is a topic that I will leave to others who know best about governmental organizations.

This is certainly a very bipartisan theme in the sense that Secretary Thompson—you have probably heard him say this over and over again; I certainly have—he believes so much in this one-agency concept that regardless of how many dedicated groups we have within the various agencies dedicated to women's health, whatever

their legislative mandate and purview, it is very important that we all speak as one voice. So it is the one-agency concept that Secretary Thompson speaks of and the fact that indeed we do have to now look at what are we doing across these agencies for menopause or for violence prevention or for heart disease. And it is hopefully my job, one of the contributions that I can make as assistant secretary, to try to take these various sections of an orchestra, perhaps, and bring to you one theme of the various contributions and initiatives.

Senator MIKULSKI. Dr. Slater, we would really welcome your doing that, and we want to hold additional hearings on this. So we really do welcome your thinking.

Dr. SLATER. Thank you, Senator.

Senator MIKULSKI. I want to note that Senator Paul Wellstone and Senator Patty Murray have arrived. Senators, I have been advised that there is a vote at 3:30, and if you have no questions for the panel or would like to submit them for the record, may we go to the second panel?

Senator MURRAY. Madam Chairman, let me just thank you for having this important hearing. I do have some questions for this panel on cardiovascular research, mostly education for women, which I think is critical, and on the issue of violence which affects women and better ways to educate our health care providers and women on that.

I will submit those for the record. I know that we have some people here waiting to testify, and we want to get them in before we have to vote.

[Prepared Statement and Questions of Senator Murray follow:]

PREPARED STATEMENT OF SENATOR MURRAY

Mr. Chairman, I want to thank you for working to put together this important hearing. As a member of this committee—as well as the Labor, HHS and Education Appropriations Subcommittee—I know how committed Senator Harkin is to improving women's health, and I'm grateful for his leadership. I am pleased to see this committee focus on women's health issues, including improvements in the Safe Motherhood Act and the Wise Women Cardiovascular Disease Screening Program.

Many women don't realize the threat posed by cardiovascular disease.

The Wise Women program, which builds on the Breast and Cervical Cancer Screening Program at CDC, would allow for greater screening and detection of potentially fatal cardiovascular disease. Improvements in reproductive health, including the Safe Motherhood Act, are critical for improving women's health. We've made a lot of progress in reducing maternal mortality rates over the last 100 years.

While health risks associated with pregnancy and child birth have improved significantly, there are still real health threats that have to be addressed. There are also huge gaps in research in post and prenatal care for women. I think the proposed changes to the Safe Motherhood Act will begin to close these gaps. However, we also need to address the issue of contraception and unintentional pregnancy.

We know that more than 50 percent of pregnancies in this country are unplanned—not unwanted—just unplanned. Prenatal care is more effective if it begins early. In fact, it's most effective when it begins prior to pregnancy. And we know that strategies for preventing birth defects are most effective prior to a woman becoming pregnant. Unplanned pregnancies can mean prenatal care is delayed by weeks. This delay can have serious consequences for both the woman and child. Access to safe, affordable family planning options is an important part of improving women's health and ensuring safe motherhood.

I appreciate all of the witnesses who are here today. Your testimony will be extremely helpful as we move this women's health initiative forward.

QUESTIONS OF SENATOR MURRAY

FOR PANEL I

Question 1. As we work to expand the Wise Women program to screen and detect cardiovascular disease, how can we best get this message out to all women? Cardiovascular disease is the number one killer of women in this country. More women will die this year from cardiovascular disease than breast and cervical cancer combined. We need to better educate women and health care providers about this threat, and we need to focus on preventing these deaths. Unlike breast or cervical cancers, there are proven prevention strategies for heart disease, yet women are not getting this information. What can we do?

Many women and health care providers are not fully aware of the health threat posed by violence. We know that the number one reason women age 16 to 35 end up in the ER is due to violence. One and three women can expect to be a victim of violence at some point in their lives, yet we have no formal or established screening. I know that HHS and CDC administer important programs aimed at reducing violence against women and the serious health consequences of this violence.

Question 2. What additional steps can we take to reduce violence against women and to ensure that battered and abused women have access to safe, quality health care?

Question 3. Can we develop uniformed screening and treatment protocols for women who are victims of violence that will be closely followed by health care providers?

One of the programs recently implemented by CDC with the help of the Chairman (LHHS) is the Folic Acid outreach and education program. This program educates women on the benefits of folic acid in preventing birth defects. I have supported this program for a number of years and have been pleased by the progress being made in providing this important prevention message to women. However, this strategy is most successful prior to pregnancy. It is still effective during pregnancy, but the guidelines clearly support women taking folic acid prior to becoming pregnant. Planned pregnancies clearly afford a better opportunity for a healthy outcome for both the mother and the child.

Question 4. What steps can we take to improve access to effective family planning services and education? Would over-the-counter status for emergency contraception, as proposed by AGOG and the AMA, reduce the number of unintentional pregnancies and improve health outcomes for the mother and child?

FOR PANEL II

Question 5. Dr. Gellhaus, in your prepared statement, you highlight the importance of family planning as preventive health. Can you expand further on why access to effective and safe family planning is important as a prevention strategy and does this include access to emergency contraception?

I have introduced S. 1990, the Emergency Contraception Education Act in order to provide women with access to education on the safe and effective use of emergency contraception. As you may know less than 12 percent of women even know that safe and FDA approved emergency contraceptives are available.

We know that cardiovascular disease is the number one killer of women. It is also the number one killer of men. However, the survival rate for men after their first

heart attack is sufficiently higher than women. Heart disease has been considered a man's disease for too long. I have seen many explanations for the different treatment and different level of care provided to women in diagnosing and screening for heart disease. The bottom line is that women are not treated with the same aggressive strategies as men. It is not just about economics or access to health care.

Question 6. How can we improve this situation and how do we get health care providers and women to seek aggressive treatments?

Question 7. Is this solely due to gender bias in research or lack of provider education?

Senator MIKULSKI. Thank you, Senator Murray.

Senator Wellstone?

Senator WELLSTONE. Madam Chair, like Senator Murray, I have questions for the record. But I think we should move on; otherwise, we will not get a chance to hear from the second panel.

Thank you, and thank you for the hearing.

[Questions of Senator Wellstone follow:]

QUESTION OF SENATOR WELLSTONE FOR MARLENE JEZIERSKI

Why is having an infrastructure within health care settings to support screening for domestic violence so important?

QUESTION OF SENATOR WELLSTONE FOR DR. GELLHAUS

In your judgment, what is the impact of lack of access to good health care on the frequency and severity of pregnancy complications?

Senator MIKULSKI. Thank you very much.

We look forward to more collaboration with you both.

The chair now calls forward Dr. Carolyn Mazure, Marlene Jezierski, Dr. Thomas Gellhaus, and Dr. Alice Ammerman.

Senator Wellstone, I understand you have a witness that you would like to introduce.

Senator WELLSTONE. Thank you. I will be brief.

Marlene Jezierski is from the State of Minnesota and is a good friend to me and good friend to Sheila.

For years, she has worked as an emergency nurse. She has published numerous articles, and specifically, Senator Murray, her articles deal with identifying domestic violence in emergency settings.

I have known Marlene's work for many years, and she has been a pioneer in the life-saving work of promoting screening for domestic violence in health care settings. She is the violence prevention educator for Allina Hospitals and Clinics in Minnesota, and she has a unique perspective, rich in experience. I could go on and on, but I will not. She has a very long resume, and I thank her so much for being here.

Senator MIKULSKI. Thank you very much.

Rather than long introductions, we want to go right to the panelists. We acknowledge that Dr. Mazure is here from the Yale University School of Medicine and is a distinguished professor of psychiatry, but she is speaking on behalf of the Society for Women's Health Research.

Marlene is here to speak as a violence prevention educator.

Dr. Tom Gellhaus, whom we just saw at the Safe Motherhood press conference, is here on behalf of the American College of Obstetricians and Gynecologists.

And Dr. Ammerman is here to also speak in terms of women's health with your extensive background in public health.

Dr. Mazure, why don't we start with you?

STATEMENTS OF CAROLYN M. MAZURE, YALE UNIVERSITY SCHOOL OF MEDICINE, ON BEHALF OF THE WOMEN'S HEALTH RESEARCH COALITION; MARLENE B. JEZIERSKI, VIOLENCE PREVENTION EDUCATOR, ALLINA HOSPITALS AND CLINICS; THOMAS GELLHAUS, M.D., DAVENPORT, IA, ON BEHALF OF THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS; AND ALICE AMMERMAN, UNIVERSITY OF NORTH CAROLINA

Ms. MAZURE. Thank you, Madam Chairman.

Thank you for the opportunity to testify today in my capacity, as you mentioned, as the chair of the Women's Health Research Coalition which was created by the Society for Women's Health Research.

In the interest of time, I would like to make three points today in my remarks.

First, I want to acknowledge the important array of programs and initiatives within the Department of Health and Human Services designed to promote the health of women and their families, and we have heard about a number of those today.

Second, I would like to emphasize the point that despite the progress that has been made that has resulted directly from many of these programs, there is much work yet to be done to serve the many populations of women that are in need of care.

Third, I respectfully submit that a critical element in accomplishing the work that is yet to be done is that Congress support by statute the various Offices of Women's Health within the Department of Health and Human Services. I would maintain that these office are important because they provide a base of operations that focus the energy and galvanize the interest that already exists within the Department of Health and Human Services for women's health.

Of equal importance, however, each of these offices is in an ideal position to supply specialized information on women and on their health needs.

So, recognizing the importance of women's health as it relates to topics managed by its agencies, the Department of Health and Human Services, as we have heard today, has really begun the process of addressing multidimensional and diverse issues that surround the field we summarize with the words "women's health."

In fact, existing offices and positions for women's health have been responsible for the initiatives that have been talked about today in some measure. Also, I would like to mention a few other examples of the important work that they do by office.

The AHRQ, Agency for Healthcare Research and Quality, senior advisor on women's health is responding to concerns expressed by the Congress and others about the unmet need for standards of care for women with cardiovascular disease.

The CDC Office of Women's Health—you have met the representative from that office today, Yvonne Green, who does a terrific job—is assessing the magnitude of the severity, treatment, and service utilization differences between men and women with asthma. This is a growing health care concern since women have higher rates of office visits, hospitalizations and deaths due to asthma and asthma-related conditions than do men.

The FDA Office of Women's Health is spearheading efforts to investigate the safety, the efficacy, and the appropriate dosage of medications in pregnant women, an area of study in which little is known, but one in which there are major implications for a woman's safe pregnancy.

HRSA's Office of Women's Health coordinates women's activities across more than 80 HRSA programs. One indication of the success of HRSA's women's health programs is that women who receive care through HRSA-supported community health centers have more up-to-date mammograms and pap smears than women nationwide.

The Office of Women's Health in the Office of the Secretary is coordinating activities and programs across many of the women's health efforts that exist within DHHS. Included in those efforts is the coordination of the DHHS Steering Committee on Violence Against Women. As you know, approximately 2 million women each year are assaulted by their partners, and domestic violence is the leading cause for emergency room visits for women in this country.

Also of great importance, the Office works with State and local governments and with private entities to form effective clinical research and training partnerships that really can leverage Federal resources and service communities across the Nation.

But as I mentioned, in spite of the fine programs, in spite of the advances, there are many examples of the work that has yet to be done. We need to understand more about the diseases and conditions that are unique to women, such as ovarian and cervical cancer, endometriosis, and postpartum disorders.

For example, we need to know why the child-bearing years have been shown to be a time of increased vulnerability to psychiatric disorders and why rates of postpartum depression have been estimated to be as high as 22 percent.

We also need a better understanding of why certain diseases and conditions have a differential impact on women and men. The example given today is cardiovascular disease; it also applies, of course, to stroke.

For example, we need to learn more about why women's risk of heart disease rises with age and why women are more likely than men to have a second heart attack within several years after their first attack.

Further, we need to know why women are more likely to die from stroke even though women and men are equally likely to have strokes.

Finally, we need a better understanding of the disorders and conditions that are more common in women, and here, there is a long laundry list—depression, breast cancer, migraines, osteoporosis, and a variety of autoimmune disorders like lupus which, for example, affects nine times more women than men, especially African American women.

And we need to tackle behaviors and conditions that are becoming more common in women, such as smoking and substance abuse. In reference to smoking, for example, we know that with the same lifetime exposure to cigarettes, the risk of developing cancer is greater in women than in men. Death rates from smoking-related

diseases are rising for women, and unfortunately now in the United States, one in four girls under the age of 18 smokes.

It is equally important that the Offices of Women's Health evaluate ways to provide women with the best treatment and services possible, and they need to investigate ways to deliver effectively the type of care that women need. In addition, they need to translate their research findings into practices, but focus on preventing disease before it develops and takes a toll on women's health and well-being.

These serious issues require carefully-thought-out comprehensive solutions from a wide-ranging partnership of governmental and nongovernmental experts, including State and local officials, nonprofit organizations, universities, and private industry. They require an unwavering commitment from the administration and Congress to look broadly, think deeply, and act smartly. That approach, however, is hampered when offices do not know from year to year what they are expected to do, if they will be funded, and at what level.

For these reasons, it is critical that Congress support by statute the various Offices of Women's Health within the Department of Health and Human Services.

In conclusion, S. 946, the Women's Health Offices Act of 2001, which was introduced by Senators Snowe, Harkin, and Mikulski and has since been cosponsored by additional Members of the Senate, takes an important step in addressing this issue. By giving statutory authority to the Offices of Women's Health in AHRQ, CDC, FDA, HRSA, and the Office of the Secretary, this legislation creates a stable and focused presence for women's health throughout the Department.

S. 946 has been endorsed by nearly 50 organizations, and with your permission, I would like to submit for the record a copy of the letter signed by these groups.

Senator MIKULSKI. Without objection.

Ms. MAZURE. Thank you again for the opportunity to address the subcommittee this afternoon. I appreciate the difficult task of trying to move forward on these complicated issues, and I thank you for your time.

Senator MIKULSKI. Thank you very much, Dr. Mazure. We really thank you for that content-rich presentation.

[The prepared statement of Ms. Mazure follows:]

PREPARED STATEMENT OF CAROLYN M. MAZURE

Thank you, Mr. Chairman, for the opportunity to testify before the subcommittee today. I am Dr. Carolyn M. Mazure, Professor of Psychiatry, Associate Dean for Faculty Affairs at the Yale University School of Medicine, Director of the Department of Psychiatry's Women's Behavioral Health Research Division, and Director of Women's Health Research at Yale—a large interdisciplinary women's health research program at Yale.

I am testifying before the subcommittee in my capacity as the Chair of the Women's Health Research Coalition, which was created by the Society for Women's Health Research approximately three years ago. The membership of the Coalition, which stands at nearly 350 persons throughout the country, includes leaders within scientific and medical research, as well as leading voluntary health associations, pharmaceutical and biotechnology companies—all with a commitment to women's health.

I would like to make three points in my remarks today. First, I want to acknowledge the important array of programs and initiatives—within the Department of

Health and Human Services—designed to promote the health of women and their families. Second, I would like to note that, despite the progress resulting from these programs, there is much work yet to be done to serve the many populations of women in need of care. And, third, I respectfully submit that a critical element in accomplishing the "work yet to be done" is that Congress support, by statute, the various Offices of Women's Health within the DHHS. These offices provide a base of operations that focus the energy and galvanize the interest within each agency regarding the health of women. Of equal importance, each of these offices is in an ideal position to supply specialized information on women and their health needs.

Mr. Chairman, I wish to thank you and the members of the subcommittee for addressing the issue of women's health and working to identify the initiatives needed to improve the health of women throughout the nation. Improving the health of women is a critically important goal because women comprise over half of the U.S. population, women are largely responsible for the health care decisions in their households, and women comprise the large majority of primary caretakers for their children and their aging parents. Thus, promoting women's health helps women and advances the health of entire families, thereby affecting far more than half the people in this nation.

As you know, the Department of Health and Human Services (DHHS) is committed to monitoring, protecting and improving the health of the nation. Recognizing the importance of women's health as it relates to topics managed by its agencies, the DHHS also has been committed to developing a focus on the health of women. Currently, there are women's health offices and positions within the agencies of the Department of Health and Human Services whose primary responsibility is to promote the health of women and their families. These women's health representatives, whose jobs are specific to the mission of each agency, are dedicated to understanding the unique roles and health concerns of women across the U.S., and to initiating and supporting programs that will advance the health of women. They provide a base of operations for focusing the energy and galvanizing the interest within each agency regarding the health of women and, importantly, they bring specialized information on women and their health needs. The programs initiated and supported by women's health staff provide for new and effective medical research studies, prevention strategies, treatment interventions and, often, make the difference between a productive life and one incapacitated by ill health and disability.

This subcommittee has a special opportunity to assure that women will receive the health-related attention needed from dedicated representatives by voting for legislation which statutorily assures that women's health offices exist within individual DHHS agencies. Support of the provisions of S. 946—the Women's Health Office Act of 2001, a bill introduced originally by Senators Snowe, Mikulski and Harkin and since cosponsored by several more of your colleagues, provides a clear demonstration to constituents and colleagues that you are ensuring opportunities to improve the health of women and their families.

Before I discuss the legislation further, I would like to provide a few brief examples of women's health programs that are the outgrowth of the women's health entities within the DHHS agencies under discussion. I believe these illustrations demonstrate the importance of leadership and coordination by women's health offices that is necessary in order to serve the fundamental health needs of women.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

As you know, Mr. Chairman, the Agency for Healthcare Research and Quality (AHRQ) is the government's leader in health services research. It supports and conducts research and disseminates information derived from research that improves access to care and the outcomes, quality, cost, and utilization of health care services. Since the reorganization of the agency, advanced by this committee under your leadership and that of Senator Frist, AHRQ has distinguished itself as a leading voice in determining what systems of service work best in healthcare.

The AHRQ senior advisor on women's health specifically is dedicated to improving the quality and outcomes of health care for women within two broad categories of initiatives. The first category relates to improvement in the quality of life and prevention of functional decline for mid-life and older women. The second relates to improvement in the quality and delivery of care for conditions that are common to women. Concurrently, the publication and dissemination of research findings referable to women's health are a high priority for the senior advisor within AHRQ. The following are but a few examples of the important work of the Senior Advisor and point to the kinds of initiatives that would be enhanced with a secured OWH. With regard to the first category of initiatives, the AHRQ women's health advisor has played a key role in responding to concern from Congress, advocacy and policy

groups about the need for standards of care for women with cardiovascular disease—the leading cause of death for women in this country. Women are more likely to manifest heart disease when they are older, and symptoms can be different than in men so that they may not be recognized. Women also receive fewer therapies and are more likely to die after a heart attack. After convening an expert steering committee of stakeholders in the health community, AHRQ in collaboration with the National Institutes of Health Office of Research on Women's Health, provided for a review of the knowledge in risk, diagnosis and treatment of cardiovascular disease in women, particularly minority women. Among the outcomes of this collaborative effort will be an evidence-based assessment for health professionals and organizations that want to develop materials for education of health care providers and patients. This result exemplifies how the efforts of the Senior Advisor complement the larger goals of the agency which, in this case, relate to the agency's commitment to translate research into practice across the U.S.

As examples of the second category of initiatives, the AHRQ women's health advisor has been instrumental in the agency's efforts to enhance management of chronic illnesses, improve quality and utilization of maternal health services for minority and other populations of women, create tools for assessing the quality of health care for women, and improve treatment outcomes for victims of domestic violence (including the elderly). As part of the analytic and communication functions related to determining the unique status of women in our healthcare system, the senior advisor was instrumental in initiating the publication of a new and useable chart-book publication on women's health status, insurance and access to care. She also successfully recommended adding questions to the ongoing Medical Expenditures Panel Survey that soon will provide detailed information on women's health expenditures.

Also of note, working with the Office of Research on Women's Health at the NIH, AHRQ supports training for the next generation of women's health researchers. Nearly half of all programs funded under the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program involve health services research components. Increasing the numbers and skills of researchers to do this work will lead the way to solutions for a multitude of our nation's health concerns.

CENTERS FOR DISEASE CONTROL AND PREVENTION

The Centers for Disease Control and Prevention (CDC) is committed to promoting health by preventing and controlling disease, injury and disability. The Office of Women's Health within the CDC is dedicated to supporting prevention research programs within and outside the CDC directed toward improving women's health, advocating for public health and policy programs created to enhance women's health, and communicating messages that promote health for women.

As one example of these efforts, the CDC OWH has focused on a serious affliction for Americans—namely, asthma. This is a growing healthcare concern for women since they have higher rates of office visits, hospitalizations, and deaths due to asthma and asthma-related complications. Yet, little is known whether women would benefit from different asthma management strategies than those used for men. The CDC Office of Women's Health is funding work to assess severity, co-occurrence of other diseases and the value of different treatments for men and women with asthma. This will be followed by the development of educational interventions to reduce the severity of asthma in women and evaluate the effectiveness of this intervention. Because chronic diseases, like asthma, can reduce ability to work and perform other necessary daily life activities, results of this work will have direct practical benefit.

Other funded projects supported by the CDC OWH focus on screening for osteoporosis in older women, expanding women's access to tuberculosis treatment, disease prevention for women working in the dry cleaning industry who are at increased risk of cervical cancer related to chemical exposure, enhanced delivery of immunizations and cancer screening to African American women enrolled in Medicare, reduction of female adolescent risk behavior, and development of a national public health action plan for diabetes in women.

FOOD AND DRUG ADMINISTRATION

The Office of Women's Health in the Food and Drug Administration (FDA) addresses differences between women and men in drug, device, and biologic testing. It ensures that FDA's regulatory and oversight functions remain gender sensitive and responsive, and it provides leadership and an integrated approach across the agency with regard to women's health issues across all organizational components of the FDA. The FDA OWH also forms partnerships with government and non-government entities to promote the FDA's women's health objectives. It does this through cost-effective and scientifically valid initiatives.

Since the office was created, the FDA OWH has funded approximately 100 scientific projects in areas of women's health, including breast and ovarian cancer, HIV transmission in women, cardiovascular disease in women, osteoporosis, the safety of breast implants, estrogen and its effects, and autoimmune diseases. Utilizing a competitive, intramural, peer-review process, OWH has funded the highest caliber scientific projects related to women's health. Projects selected are those that can affect the regulatory process and offer the highest potential yield in new information on women's health in a minimum amount of time.

Currently, the FDA OWH has provided funding to investigate the safety and effectiveness of prescription medication used during pregnancy. This work is designed to understand the metabolism and effectiveness of medications for high blood pressure in pregnant women while also examining whether important dosing information can be ethically and economically obtained from studies conducted in pregnant women. Because medications are not tested in pregnant women prior to the medications coming on the market, this investigation seeks to develop model studies for measuring the drug metabolism for products that are in fact used during pregnancy. For some women with conditions such as high blood pressure, epilepsy, or an autoimmune disease who must continue or begin to take prescription drugs for their medical conditions during pregnancy, results of this work are vital to their health and their potential to have healthy children.

The FDA OWH also has coordinated action to develop regulatory policy related to such topics as women as subjects in clinical trials. It has undertaken outreach programs such as "Take Time to Care" that alert women to the importance of the correct use of medicines for themselves and their family members. Millions of Americans have participated in this educational campaign that included dissemination of copies of a brochure entitled "My Medicines" published in English, Spanish and several other languages. An upcoming "Take Time to Care" campaign on diabetes will provide valuable information for women to be aware of the impact of this disease and methods of prevention and management.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

The mission of the Health Resources and Services Administration (HRSA) is to assure access to health care that has no disparities for underserved, special needs, and vulnerable populations. HRSA promotes health care infrastructure and systems development, and training for a diverse and culturally competent health professions workforce. The HRSA OWH is the principal advisor for agency activities and policies that address women's health.

As a consequence of lower employment rates among women, lower pay and a greater likelihood to be in a job that does not include health benefits, unequal access to health care is a problem more likely to affect women. In fact, about 15 percent of women under the age of 65 years lack health insurance and many women are underinsured. The HRSA Office of Women's Health plays an important role in assuring the delivery of health care services to medically underserved and underinsured women. It coordinates women's activities across more than 80 HRSA programs, working to ensure that the health needs of these women and girls are addressed across the life span. One indication of the success of the office and, as a result, of the agency is that women of childbearing age who are served in community-based health facilities have higher rates of mammograms and pap smears than comparable women across the nation.

"The Bright Futures for Women's Health & Wellness" program is just one example of a program managed by the HRSA OWH. This program is designed to provide health care information for every woman served, regardless of her education or ethnicity, and for every health care provider within the community health care system so that every clinical encounter is an opportunity to practice disease prevention and education. This community-wide health promotion program includes materials development and training for community health professionals and families, as well as an evaluation component to refine the program. Another example of a HRSA program, in collaboration with CDC and the States, is "Statewide Partnerships in Women's Health." The partnerships encourage statewide collaboration in developing the capacity among partner organizations to leverage resources and establish an integrated approach to coordinating health services for underserved women.

In addition, the HRSA OWH, at the request of Congress, has performed detailed assessments of women's health curricula in medical, dental and nursing schools. It also has developed a model medical school core curriculum on women's health and strategies for implementation along with summaries of opportunities to improve the dental and nursing curricula. Assuring the nation's health care providers are edu-

cated with the most up-to-date information is another step to assuring this nation's wellbeing.

OFFICE ON WOMEN'S HEALTH IN THE OFFICE OF THE SECRETARY

The Office on Women's Health in the Office of the Secretary is the focal point and advisory body in DHHS for developing and advancing women's health research, health services, and public and professional education across the public health service. One crucial component of the Office's effort is its coordinating function. Just as the Secretary's Office weaves together the common threads of the entire department so, too, does OWH weave together those common threads related to women's health services, treatment and research throughout DHHS.

In this role, the Office oversees the Coordinating Committee on Women's Health, comprised of senior level representatives throughout the DHHS, for the purpose of fostering collaboration and coordination in women's health initiatives and activities across the DHHS. The OWH oversees regional women's health coordinators throughout the country assisting with State and community involvement in eliminating health disparities. The Office regularly coordinates DHHS activity on key issues such as domestic violence through the DHHS Steering Committee on Violence Against Women. Still more coordinating and oversight activities include working with representatives from all agencies of the Federal Government on priority areas in women's health which are regularly updated and outlined on the National Women's Health Information Center web site managed by the DHHS OWH. The Women's Health Information Center offers a single entry point for access to more than 4,000 publications and 1,600 organizations addressing more than 800 health topics.

The DHHS OWH also has been responsible for multiple public information campaigns such as "The Pick Your Path to Health Campaign" which provides comprehensive, culturally-appropriate health information for women of color. Another campaign, in which the OWH partnered with the Society for Women's Health Research, focused on educating young women regarding maintenance of behaviors leading to healthier lives.

The OWH also has funded and supported National Centers of Excellence in Women's Health across the country that provide important models for delivering care to women while offering educational and research opportunities. In this regard, the OWH in the Office of the Secretary, in collaboration with HRSA and the Office of Minority Health, has been responsible for establishing seven Community Centers of Excellence in Women's Health. These Centers identify, support and replicate promising community based approaches to women's health services, training, research and outreach in various parts of the country.

CONCLUSION

Mr. Chairman, women's health has made important strides in the last decade as a consequence of it being increasingly recognized as a national priority. Through the offices and positions for women's health within the DHHS, efforts have been successful in initiating research studies that examine major women's health issues, education campaigns that enhance public awareness of women's health concerns, and clinical services and screening projects that improve women's health. We need to remain vigilant that our recent successes in addressing the health of women are not followed by a decline, because much work remains to be done for many different subgroups and populations of women in need of care. We must acknowledge that there are many examples of work that has yet to be done.

- We need to understand more about the diseases and conditions that are unique to women such as ovarian and cervical cancer, endometriosis, and post-partum disorders. For example, we need to know why the childbearing years have been shown to be a time of increased vulnerability to psychiatric disorders, and why rates of post-partum depression have been estimated to be as high as 22 percent.
- We also need a better understanding of why certain diseases and conditions have a differential impact on women and men, such as cardiovascular disease and stroke. For example, we need to learn more about why women's risk of heart disease rises with age and why women are more likely than men to have a second heart attack within several years after their first attack. Further, we need to know why women are more likely to die from a stroke, even though women and men are equally likely to have strokes.
- Finally, Mr. Chairman, we need a better understanding of the disorders and conditions that are more common in women such as smoking and substance abuse. In reference to smoking, for example, we know that with the same lifetime exposure to cigarettes, the risk of developing cancer is greater in women than men. Death

rates from smoking-related diseases are rising for women and unfortunately, one in four girls under the age of eighteen now smokes.

And it is equally important that the Offices' of Women's Health evaluate ways to provide women with the best treatment and services possible and they need to investigate ways to deliver effectively the type of care that women need. In addition, they need to translate their research findings into practices that focus on preventing disease before it develops and takes a toll on women's health and well-being.

There is a clear need to stabilize representation for women's health within the DHHS in order to maintain current productive efforts, coordinate existing and developing initiatives, and integrate new topics of significance to women's health into each agency. This can be accomplished by establishing structured offices by statute and, subsequently, assuring future funding commensurate with the mission of each office.

Currently, actual designated representation for women's health varies across agencies. The women's health representatives have varying relationships with their agencies based on a number of factors including the mission and function of the office or position within the agency, the reporting structure for the office or position, whether there is a budget line for the office or position within the agency, and whether the office or position is present by way of statute.

Mr. Chairman, these serious issues require carefully thought-out, comprehensive solutions from a wide-ranging partnership of governmental and non-governmental experts, including State and local officials, nonprofit organizations, universities and private industry. They require an unwavering commitment from the administration and the Congress to look broadly, think deeply, and act smartly. That approach, however, is hampered when offices do not know from year to year—and sometimes from month to month—what they are expected to do, if they will be funded and at what level. For these reasons, it is critical that Congress support by statute the various Offices of Women's Health within the DHHS.

I would respectfully submit to the subcommittee that one of the most effective and efficient means of addressing women's health needs would be to include provisions that are substantially similar to those in S. 946, the Women's Health Office Act of 2001 bipartisan legislation introduced by Senators Snowe, Mikulski and Harkin, in any comprehensive legislation. These provisions, which would authorize appropriations through 2006, would enable and enforce a level of security critical for the future of these offices.

Only through strong support from the Congress and the Administration can these offices address the complex and very specialized area that is women's health. It is critically important that dedicated representatives for women's health are "at the table" at the highest levels, and are participants in designing and implementing the agenda for an agency, whether it is the AHRQ, FDA, CDC or HRSA. When each agency has a women's health office by statute, a clear and direct reporting structure, and a budget line for women's health commensurate with its mission, it will be possible to build upon the success of the current women's health offices and positions, and further evaluate the impact and voice of the office within the agency.

Women's health has reached a critical point of awareness in America, and only with continued and dedicated representation will it remain a significant and growing part of our national health agenda for this new century. There is a positive, constructive effort to assure that this message is heard. The various offices, coordinators and advisors on women's health that exist throughout the Department of Health and Human Services personify that voice. On behalf of the Women's Health Research Coalition, I would respectfully request that the subcommittee include statutory authority for Offices of Women's Health in the Office of the Secretary, AHRQ, FDA, CDC and HRSA in any legislation addressing women's health that it may advance. The presence of women's health offices makes a difference to the health of American women and, thus, will benefit us all.

S. 946 has been endorsed by nearly 50 organizations and, with your permission, I would like to submit for the record, a copy of a letter signed by these groups. Mr. Chairman, thank you for the opportunity to address the subcommittee this afternoon. I appreciate the difficult task you are undertaking and would be pleased to answer any questions you or any other member of the subcommittee may have concerning my remarks.

Endnote: Information has been drawn from the Report to Congress on Women's Health Offices, Programs and Activities in the Department of Health and Human Services, Arthur L. Lawrence, Ph.D., Assistant Surgeon General, March 2001; Mazure et al., J Women's Health & Gender-Based Medicine, 10(9), 2001; (1)DHHS web sites.

WOMEN'S HEALTH RESEARCH COALITION,
WASHINGTON, DC 20036,
May 14, 2001.

Hon. BARBARA MIKULSKI,
U.S. Senate,
Washington, DC 20510.

DEAR SENATOR MIKULSKI: As organizations representing millions of patients, health care professionals, advocates and consumers, we thank you for your leadership in introducing the "Women's Health Office Act of 2001." We enthusiastically support this legislation and look forward to its passage.

Historically, women's health has not been a focus of study nor has there been adequate recognition of the ways in which medical conditions solely or differently affect women and girls. In the decade since attention began to focus on disparities between the genders, scientific knowledge has accumulated alerting us to the importance of considering the biological and psychosocial effects of sex and gender on health and disease.

We support the work of the offices of women's health in ensuring that women and girls benefit equitably in the advances made in medical research and health care services. The legislation will provide for the continued existence, coordination and support of these offices so that they analyze new areas of research, education, prevention, treatment and service delivery.

We appreciate your firm commitment to improving the health of women throughout the nation.

Sincerely, Women's Health Research Coalition; Society for Women's Health Research; American Association of University Women; American Medical Women's Association; American Osteopathic Association; American Physical Therapy Association; American Psychological Association; American Urological Association; Association for Women in Science; Association of Women Psychiatrists; Association of Women's Health, Obstetric and Neonatal Nurses; Center for Ethics in Action; Center for Reproductive Law and Policy; Center for Women Policy Studies; Church Women United; Coalition of Labor Union Women; General Board of Church and Society, the United Methodist Church; Girls Incorporated; Hadassah; Jewish Women's Coalition, Inc.; McAuley Institute; National Abortion Federation; National Association of Commissions for Women; National Center on Women and Aging; National Coalition Against Domestic Violence; National Council of Jewish Women; National Organization for Women; National Partnership for Women and Families; National Women's Health Network; National Women's Health Resource Center; National Women's Law Center; NOW Legal Defense and Education Fund; Organization of Chinese American Women; OWL; Religious Coalition for Reproductive Choice; Society for Gynecologic Investigation; Soroptimist International of the Americas; The General Federation of Women's Clubs; The Woman Activist Fund, Inc.; Voters for Choice Action Fund; Women Employed; Women Heart: The National Coalition for Women with Heart Disease; Women Work!; Women's Business Development Center; Women's Health Fund at University of Minnesota; Women's Institute for Freedom of the Press; Women's Research and Education Institute; YWCA of the U.S.A.

Senator MIKULSKI. Dr. Ammerman, I am going to turn to you now and then to Ms. Jezierski and then to Dr. Gellhaus and ask you to proceed. I did not give you enough due when I failed to introduce you as someone who comes here with not only a doctorate in public health, but you are an associate professor of nutrition at the School of Public Health at the University of North Carolina, Chapel Hill, which is, outside of the Hopkins School of Public Health, one of the great ones.

So much that we hear about is related to diet. We hear about this all the time, and yet it seems to be lacking in any kind of consultative way. Would you present that, please?

Ms. AMMERMAN. Thank you.

I am not sure that it is mentioned on the program, but I am here actually to talk about the Wisewoman program in particular and our experience in North Carolina.

I am very pleased to talk about Wisewoman, because I believe it really has great potential to benefit disadvantaged women who, as we have heard, are at very high risk for chronic disease but are really poorly-served by our health care system.

I will speak very briefly about what Wisewoman is—you have heard much about that—and what some of the challenges and successes in North Carolina have been, and then how our experience can benefit other Wisewoman States and other disadvantaged women across the country.

As you have heard, Wisewoman builds on an existing prevention program, the National Breast and Cervical Cancer Early Detection Program. We like to say about Wisewoman that it offers one-stop shopping so that women who come in to get screened for breast and cervical cancer also get a chance to be screened in terms of heart disease and then, more important perhaps, that we provide interventions in terms of dietary and physical activity, and smoking cessation.

In North Carolina, we received funding for Wisewoman in 1995 when it first began. We started with an existing nutrition intervention program that we called Food for Heart, and we expanded it to include physical activity, smoking cessation, osteoporosis prevention, diabetes control, and we renamed it the New Leaf program.

Senator MIKULSKI. Dr. Ammerman, I am going to interrupt here. The vote has started, and we will have to leave here in about 15 minutes, and there are five votes scheduled in a row.

This is in no way to ask you to shrink your testimony, but I guess it is. So I am going to ask you if you could summarize the Wisewoman program, and then we will go to Ms. Jezierski and Dr. Gellhaus, because after the presentations, we will submit questions only because these 5 to 12 votes are going to occur.

Would you please proceed, but know that that is how we are going to be operating.

Ms. AMMERMAN. OK. I tried to mark a few key sentences in my testimony, so I will go to them.

Essentially, I think you have heard what the Wisewoman program does. I think it is really extremely well-designed to reach a very high-risk population, and we have some very practical strategies that we have developed.

We developed this New Leaf intervention which is based on low-literacy materials development for women who do need materials that are practical for their lives. We focus on walking rather than aerobics classes and things that may not be appropriate for lower-income women. We focus on modifying Southern-style recipes rather than expecting people to eat tofu and bean sprouts. So we try to make an attempt to really make it relevant to the people who are in the program.

The program now has been expanded to 12 programs in 11 States. We have worked with a variety of the other programs to develop materials as well. We started with New Leaf, and we have worked with the Alaska program, but we found that "new leaf" was not a useful term, because people do not think of turning over a new leaf in either a Native Alaskan population or a Hispanic population; so in Alaska, they renamed the program Traditions of the

Heart and really built in a lot of Native American traditions, and the Hispanic version translated is Healthy Diet, Happy Heart.

So these things are being incorporated across the country and adapted to reach the populations at highest risk.

I will go to my summary paragraph. In summary, Wisewoman reaches a very highly vulnerable population with an efficient screening and prevention program as the rates of chronic disease soar and health care resources remain limited.

I would like to thank Congress and the CDC for recognizing that financially disadvantaged women and the providers who serve them need substantial help if they are to fight off heart disease, diabetes, and obesity.

I think it is critical that all States have the opportunity to provide the benefits of Wisewoman to their disadvantaged women. At the same time, I think expansion of the program should be done thoughtfully, with adequate resources devoted to evaluation so that we can determine the most cost-effective approaches to reach these women.

Thank you.

Senator MIKULSKI. That was outstanding.

I just want to say to you, Dr. Ammerman, that I am going to be holding a hearing in my subcommittee on Aging later on this summer on obesity and diabetes and a focus on what are the programs and the whole issue of prevention, and we are going to invite you back—in fact, we would like to invite all of you back.

[The prepared statement of Ms. Ammerman follows:]

PREPARED STATEMENT OF ALICE AMMERMAN, DRPH, RD

Hello, my name is Dr. Alice Ammerman. I am an Associate Professor in the Department of Nutrition, Schools of Public Health and Medicine, at the University of North Carolina at Chapel Hill. My research focuses on developing and evaluating innovative approaches to nutrition and physical activity interventions for minority and disadvantaged populations. Over the last 20 years, I have developed, tested, and refined the program: New Leaf, Choices for Healthy Living, which is designed to be culturally sensitive and clinically feasible for application by front line public health workers who face multiple demands with limited resources. In this work, I have collaborated with my husband who is a general internist and has practiced in community health centers in rural North Carolina. I became involved with WISEWOMAN in 1995 soon after the program began. In addition to serving as the lead nutrition and physical activity interventionist and evaluator for North Carolina, my staff and I have assisted many other WISEWOMAN States with adapting the New Leaf intervention for their regions and have consulted with the CDC regarding future directions of the WISEWOMAN program.

I am very pleased to speak with you today about the WISEWOMAN program, because I believe it has great potential to benefit disadvantaged women who are at high risk for chronic disease, but poorly served by our health care system. I will address the following three questions:

(1) What is the WISEWOMAN Program?

(2) What have been the challenges and successes of the North Carolina WISEWOMAN program?

(3) How can our experience benefit other WW States and disadvantaged women across the nation?

(1) What Is the WISEWOMAN Program?

Briefly, WISEWOMAN is designed to improve the health of financially vulnerable women. Heart disease is the leading cause of death among women, and we are experiencing epidemic rises in obesity and diabetes particularly among disadvantaged women. Because most of the original research on CVD was done on men, heart disease is often not viewed as a "women's problem." However, heart disease kills more than 370,000 women each year and affects 1 in 4 women over the age of 65. Women are more likely to: delay seeking care after the onset of heart attach symptoms, suf-

fer a severely damaging heart attack, and suffer a second heart attack within six years of the first one. They are less likely to: receive preventive counseling from their physicians on their CVD risk factors, have their heart attack symptoms recognized by a health care provider, or be enrolled in rehabilitation programs after a heart attack.

Women in North Carolina are particularly vulnerable. North Carolina sits firmly in the "stroke belt," where deaths from heart disease and stroke exceed the national average. Among North Carolina women, the heart disease death rate for all women is 400/100,000. However, disparities exist, with rates of 513/100,000 for African American women, 485 for Native Americans and 375 for Caucasian women.

The most cost effective approach is to prevent or delay the onset of these diseases through lifestyle modification—improved diet and increased physical activity. WISEWOMAN does this by building on an existing program—the National Breast and Cervical Cancer Early Detection Program. The beauty of WISEWOMAN is that these women who may hold multiple jobs or face transportation problems, can make just one stop and receive both services. In North Carolina, WISEWOMAN is a partnership between our State and local health departments and the UNC Center for Health Promotion and Disease Prevention, which is one of 26 prevention research centers at universities across the nation funded through legislation initiated by this committee.

(2) What Have Been the Challenges and Successes of the North Carolina WISEWOMAN Program?

North Carolina received funding from CDC for a WISEWOMAN grant in 1995 when the program first began. We have built our intervention around an assessment and counseling program, called Food for Heart, that we had developed and tested over the past 15 years in community health centers and local health departments. The design of Food for Heart was based on sound behavior change theory as well as personal experience "in the trenches" of public health care delivery. Our studies had demonstrated the effectiveness of this program in improving diet, curbing weight gain, and reducing serum cholesterol. In our WISEWOMAN proposal, we expanded Food for Heart to include physical activity, smoking cessation, osteoporosis prevention and a diabetes module, and renamed it "New Leaf, Choices for Healthy Living." This truly allows "one stop shopping" for women's health needs. (ref. New Leaf Notebook)

In the first phases of NC WISEWOMAN, we have tested the New Leaf intervention in 42 counties, reaching over 4,000 women. We learned much about the challenges of implementing and evaluating such a program in resource-strapped health departments. For example, public health staff lacked culturally appropriate intervention materials, lacked confidence in their ability to help patients make lifestyle changes, and have very limited time to counsel. The New Leaf addresses these problems by providing easy to read, culturally relevant materials designed to guide counseling by practitioners who have little background in nutrition. We have further streamlined the intervention and built in more flexibility, such as a telephone counseling option for those with transportation problems.

The response from participants and front line staff has been very positive. The staff feel that they finally have the tools they need, and participants are pleased that the approach is relevant to their lives. For them, walking with friends, as promoted by our intervention, is much more realistic than aerobics classes and jogging. Similarly, lower fat recipes for southern favorites are better received than exhortations to eat tofu and beansprouts! Describing her experience in delivering the program, Betty Person, a nurse in Person County North Carolina said "These ladies have not had anyone sit down with them and take the time to discuss healthy eating habits and the importance of exercise . . . I can see the light bulbs go on. The patients appreciate the interest shown in them by the phone calls to check on their progress, mailings, and handouts; especially the New Leaf notebook and cookbook. We have a few patients that are now being treated for diabetes because of the blood work done through the WISEWOMAN Program. Some wanted their cholesterol checked but did not have the money to have the blood test. The WISEWOMAN Project has enabled them to do this."

Quotes from women in the South Central Foundation WISEWOMAN program in Anchorage Alaska include the following:

"Some things I already knew but didn't practice. Some things I didn't know and appreciate the enlightenment on some topics. I enjoyed all the classes and am eager to practice what I have learned. There was something about the setting that was making me willing to change for the better."

"It was very organized and planned. The leaders were very thoughtful to what the group wanted and sensitive to the Native way. Everyone was made to feel welcome and it was easy to talk."

"I think it is wonderful that this program is helping to maintain, protect and practice preventive maintenance for Native Women. It would be great to expand for all people Native and NonNatives and educate people about good health practices. It is also a great way to curb and cut down on rising health care costs. Thank you very much!"

Given the unique role of women as gatekeepers and nurturers in their families and communities, WISEWOMAN has the potential to positively effect a much broader population as the participants share and apply what they learn. Many health department staff in North Carolina have commented on their own successful lifestyle changes inspired by the program and talk about "taking it home" to the family. One public health nurse in North Carolina said "Several patients have told me their husbands are supposed to be on low fat, low sodium, low sugar diets due to heart disease, diabetes, or hypertension. The wives are delighted to have this information to better help their husbands eat healthier, so it is benefiting the whole family. In the Anchorage-based WISEWOMAN program, one Native Alaskan woman said "This has been a fabulous class for me and my husband! I shared all the information with him. I am motivated to exercise and eat right. This is the best I have felt in years. I have lost nine pounds!"

Perhaps the biggest challenge of the NC WISEWOMAN program has been collecting data of adequate quality to allow us to determine the health benefits of participation. County health department staff are not trained in research methods and have little time or inclination for extra paperwork. To send research assistants to each county would be enormously expensive. We have some reliable evidence of positive dietary change based on WISEWOMAN, but are continuing to work on the best approach to collect good health outcome data.

(3) How Can Our Experience Benefit Other WISEWOMAN States and Disadvantaged Women Across the Nation?

CDC has now expanded WISEWOMAN to a total of 12 programs in 11 States. The North Carolina team has shared our experiences with these new sites, and produced a practical manual to help others integrate WISEWOMAN into existing health services (ref. monograph). Some WW programs are developing their own approach to interventions, while a number have chosen to adapt our New Leaf intervention. Two groups in Alaska have adapted the New Leaf for a Native Alaskan population (ref. Traditional of the Heart). Other States making more modest changes in New Leaf include Vermont, Connecticut, South Dakota, and California. We are also testing a recently completed Spanish translation of the New Leaf Materials (ref. Vida Saludable, Corazon Contento). These collaborations have highlighted the importance of culturally tailoring lifestyle interventions. In North Carolina we eat pork chops and worry about heat and humidity while exercising in the summer. In Alaska, they eat moose meat and worry about avalanches and bears while being active in the winter. Even the name of the program needed to change. The idea of "turning over a new leaf" does not exist in either Native Alaskan or Hispanic Cultures, thus the program was renamed "Traditions of the Heart" in Alaska, and "Vida Saludable, Corazon Contento" (Healthy Living, Happy Heart) in the Hispanic version.

To further assist other States with intervention development and implementation, we are developing a week-long national training course for WISEWOMAN project staff, safety net providers, and others implementing programs to improve the diet of financially disadvantaged populations. This course will be offered for the first time in October, 2002.

We also continue to develop and refine our approach to WISEWOMAN screening and intervention in hopes that it will ultimately be useful to other States. We have recently been funded by CDC to test new strategies aimed at improving the efficiency of the program by using lay health advisors to link participants with existing community resources, identifying neighborhood influences on diet and physical activity through geocoding, and using group education opportunities. Fortunately, this funding will also allow us to evaluate the health outcomes of the program more rigorously by focusing data collection efforts on a smaller number of representative sites. This evaluation will include a cost-effectiveness analysis.

As the rates of chronic disease soar and health care resources remain limited, the WISEWOMAN funding has helped our North Carolina team develop and refine the New Leaf counseling tool and in turn help others adapt it for their use. The funding has allowed us to build capacity in local heath departments to provide substantially improved health promotion interventions and to link with existing complementary

public health resources in the community. We'd like to thank the Congress and CDC for having had the foresight in 1995 to recognize that financially disadvantaged women and their providers need substantial help if they are to fight off heart disease, diabetes, and obesity. In my estimation, the WISEWOMAN projects are providing this much needed help to women and their families. I think it is critical that all States have the opportunity to provide the benefits of WISEWOMAN to their disadvantaged women. At the same time, I believe that expansion of the program should be done thoughtfully and with adequate resources devoted to evaluation so that we can determine the most cost-effective approaches to reach these women and improve their health.

LIST OF RELEVANT WEBSITES FOR WISEWOMAN

WISEWOMAN Web site http://www.cdc.gov/wisewoman
University of North Carolina at Chapel Hill (New Leaf and WISEWOMAN Manual) http://www.hpdp.unc.edu/WISEWOMAN
South East Alaska Regional Health Consortium (SEARHC) WISEWOMAN http://www.searhc.org
South Dakota WISEWOMAN http://www.state.sd.us/doh/Disease2/cancer.htmn
American Heart Association http:/www.americanheart.org
National Heart, Lung, and Blood Institute (NHLBI) http://www.nhlbi.nih.gov/

Senator MIKULSKI. Marlene, please proceed.

Ms. JEZIERSKI. I am truly honored to be here, and I am so thrilled that domestic violence is a high priority.

You have heard my background; I will not give you much more on that. But I want to tell you a couple of things. I have worked very extensively in the last decade in developing educational programs for health care providers, and I have learned a lot. I have learned from advocates, I have learned from survivors, and I have learned from patients and health care professionals.

When we do our work well, it is marvelous, and when we do not, it can really stink. When we do it well, we have things happen like an obstetrics doctor told me that he had seen a patient who acknowledged abuse, he spoke with her, and a year later, she came back to see him, and she said, "Thank you so much for what you did for me a year ago." And he looked at her, and he said, "Tell me what was so helpful."

She said, "You told me, you do not deserve it."

Those words are powerful medicine, and if we can teach people how to say them right, we can save lives.

I have four main points that I will really try to truncate with respect to the time. First, I think we recognize that physical, sexual, and psychological abuse has a huge impact on women's health, and many of the processes that were discussed today are part of what can happen to women in abuse relationships—not just physical injury, but chronic chest, abdominal, and pelvic pain, migraines, irritable bowel syndrome, fibromyalgia—a whole, huge list of things that overlap into all of these other presentations today.

In addition, individuals in abusive relationships indulge in—and "indulge" is not the right word—injurious health behaviors. They are known to smoke more. They are known to be heavier. There is known to be a high rate of substance abuse in these patients.

My second point is that health care professionals must be well-educated, and this is a key message in Senator Wellstone's proposed legislation. If they are not educated well—and out there right now, many have no education at all, or little; they might squeeze it in on their lunch hour at the clinic when they have a production level to adhere to, so they are in and out as fast as they

can—it is inadequate for them to learn how to be sensitive and responsive.

Little or no education not only results in little or no screening, but sometimes it is offensive, and at worst, it can be dangerous. People have asked people about their safety in front of abusers. They have called abusers on the phone after they have left. So it is a key elemental piece. They must be well-educated.

Third is that screening should be universal. You cannot tell someone who is abused by looking at them, so you must ask, and we must ask everyone. There is a precedent for that, and it is in blood pressure screening. Twenty-three percent of people develop hypertension. Twenty-five percent of women have a lifetime history of physical or sexual abuse.

There is a real classic example of that from an urgent care visit of a patient who had a bee sting in one of our urgent cares. She was screened, she said no, she went home. She sent a fax the next day. The fax described the horrific life that she was experiencing, and the staff was able to call her. At the end, she said, "Please put this in my medical record in case something happens to me." This was not a call for putting something in a medical record; this was a cry for help. Had we not routinely screened, this woman never would have gotten help.

Fourth, a successful program requires partnerships with domestic violence agencies and infrastructure—and that again is in Senator Wellstone's legislation. And we cannot just do the education and then set them loose. I have seen that. I have seen it fail, I have seen it struggle. Part of it is in terms of partnerships with domestic violence agencies—this is how our patients receive help. We do not know how to do that. The experts are the advocates, and we need to connect our patients with them preferably in person.

The other piece is that you cannot just have them hanging out there. One of Jackie Campbell's recent articles discussed that you can have all the other things in place, but if you do not have administrative support, you will not get a good program and be able to sustain it.

When I was a manager in the emergency department, I actually had it in the performance review; so if they did not screen, I had a conversation with them—I was very nice, but I had a conversation with them.

Finally, one example from Allina's experience is at United Hospital in St. Paul. After 4 hours of mandatory education, our identification and referral rate to advocacy services—we do have an onsite advocacy service there—shot up from one or two per quarter to 100 per quarter. We have served almost 2,000 women, and I know we have helped improve their health. It is a journey, and the way we need to learn how to serve them is to be sensitive, nonjudgmental, accepting, and not tell them what to do. And you cannot learn how to do that unless you are educated. Some people can.

One example of that is a physician who wrote a prescription: "Leave your husband." So I cannot say it loud enough.

This is the last story. A survivor told me this story. She said that she had had her head bashed in the driveway multiple times, went to the ER with a head injury, and she said she believed she was

dying—she felt that she was floating above her body—and she said, "If they had asked me, I would have spilled my guts. But nobody asked, and I went back with my abuser."

This concludes my testimony. Thank you so much.

Senator MIKULSKI. Outstanding. Thank you very much.

[The prepared statement of Ms. Jezierski follows:]

PREPARED STATEMENT OF MARLENE B. JEZIERSKI, RN, BA

The purpose of my testimony is to discuss why domestic violence is a health care problem and must have high priority in legislation dealing with women's health. In my work at Allina Hospitals and Clinics, a health care system that owns 12 hospitals and 40 clinics, I have worked as a violence prevention educator and coordinator, educating health care professionals and developing systems that support ongoing, routine and effective screening for domestic violence.

I have worked with health care professionals for more than a decade teaching them why they should ask their patients if they are being hurt by someone in their life and how they should do that. I have worked with leaders incorporating supportive infrastructure so abuse screening practices can be sustained. Working with front line providers I understand the barriers they encounter and what it takes to establish routine screening. I have heard dozens of survivor stories. I have spent countless hours with domestic abuse advocates I know from these experiences that hundreds of abuse victims can be helped. I have heard many stories from domestic abuse victims describing how their lives have been positively impacted by health care professionals' sensitivity and knowledge. I know screening and referral in the health care setting helps battered women. I believe our work has saved lives.

There are four recommendations I would like to make.

- First, to assure competent screening and intervention, health care professionals must be educated in schools and the clinical environment.
- Second, a health care "best of practice" should be established; adults and teens should be universally screened for histories of family and domestic violence.
- Third, partnerships should be developed between health care and domestic abuse advocacy services. The most preferable arrangement is provision of on-site advocacy.
- Fourth, infrastructure must be in place to maintain sustainability of abuse screening protocols. This includes measurement, leadership support, policy changes, forms revisions and clearly stated performance expectations.

WHEN ABUSE SCREENING IS DONE PROPERLY

During an annual physical at one of our clinics, a gynecologist screened his patient for domestic abuse. She disclosed her history of abuse by her husband. The physician's response was kind and very gentle. He said to her "You don't deserve that". A year later when she returned for her annual visit, the woman looked at him with great appreciation and said "Thank you for what you said to me when I was in here last year." Not remembering, the physician asked his patient what he had said that was so helpful. She repeated "You said 'you don't deserve that'. I want you to know that I am no longer in an abusive relationship. What you said to me that day helped me make a change".

This scenario has been repeated many times in our health care settings. It exemplifies the value of screening all of our patients. Women want us to ask and to care.

DOMESTIC VIOLENCE AND WOMEN'S HEALTH

Domestic violence has been identified as a significant health problem by every major professional organization. The Joint Commission on Accreditation of Healthcare Organizations requires institutions it accredits to identify family violence victims.

Incidence of Abuse

Research documenting the incidence of abuse includes:

- 30 to 40 percent of murdered women in the U.S. are victims of intimate partner violence (IPV).
- 37 percent to 54 percent of women seen in the Emergency Department have been abused by an intimate partner at some point in their lives.
- Each year over 2 million women experience intimate partner violence severe enough to cause physical injury.

• At least 13–30 percent of all women in the U.S. will experience one or more incidents of IPV in their lifetime.
• 20 percent of pregnancy-associated deaths were caused by homicide.
• The incidence of violence during pregnancy occurs at a rate of 4 percent to 8 percent.
• 21 percent to 34 percemt of women experience emotional abuse, a major factor contributing to chronic health problems.

EMOTIONAL ABUSE: A SURVIVOR'S STORY

Response to Abuse

If he had hit me, I wouldn't think it was my fault. Instead he told me "everything" was my fault and I kept quiet to keep peace. Eventually, I guess I believed him. If he had tried to kill me, everyone would agree I needed to leave him to preserve my life, and support me when I did. Instead, he tried to kill my spirit, and I struggle alone with a sense of failure and inadequacy, questioning what have I done wrong, and why did I have to leave.

If he had been a thief, I would have been afraid of him and stayed away. Instead, he was a smooth-talking charmer whose heart was willing to take from my soul, and then tell me what I owed him. I continually search my soul and seek the Lord and His wholeness. I wonder why I allowed him to hurt me so many times before I finally realized he didn't love me, instead of wondering why he had no conscience in doing what he did to me. If he had used fists or weapons, I would have thought it was his action and his decision. But since he used words, I blame myself. I should have known. I shouldn't have allowed it. If he had been willing to listen when I tried to talk, maybe that twisted relationship could have been healed as we allowed the truth to enter. Instead, he would get angry and turn my concern into what was wrong with me, twisting it further. At first I innocently believed him. Later I got angry. Then I doubted myself. Then I was broken. When I gave up trying to have a voice, I knew I had to leave.

Of course I want to forgive him, but it's scary to even acknowledge that a person can treat someone the way he treated me. So even though I found the strength to leave, even though I've been gone for two years, I struggle daily to get free. When will I be free of all the wounds, received at the hand of someone who claimed to love me, free of the self-doubt and self-rejection? When will I see the sins as belonging to him instead of me? (Anonymous, Registered Nurse, Health Care Consultant, survivor of domestic abuse)

Domestic Abuse Contributes to Poorer Health

Intimate partner violence is associated with many adverse health effects. The obvious are trauma caused by physical and sexual violence. Many additional health effects, most of which are difficult to treat, include: chest pain, sleeping/eating disorders, abdominal pain, intestinal disorders, miscarriages, substance abuse, depression, anxiety, chronic headaches, chronic pain, fatigue, fibromyalgia, sexually transmitted diseases, urinary tract infections, and post-traumatic stress disorder. Childhood sexual abuse has a significant relationship to health problems and abuse in adulthood.

SURVIVOR STORY: THE HEALTH EFFECTS OF ABUSE

Would You Recognize Me if You met Me?

Would you recognize me? I could be your sister, your daughter, your mother or your wife.

I grew up in a loving, supportive, caring family. My parents have been married for over 55 years. They taught us to care for and about one another. I became a nurse. In my professional experiences, I saw the effects of abuse on patients and their families. Now, after thirty years, I carry my own diagnoses of dysthymia which led to depression, post traumatic stress disorder, hypothyroidism, fibromyalgia and am currently undergoing a cardiac workup. My psychotherapist and I agree that my diagnoses are the result of the myriad of abusive experiences I have endured over the past thirty years. My family and I have undergone marital and family counseling, school counseling, physical therapy and hospitalizations. My ex-husband(s) have undergone domestic abuse counseling and anger management. My ex-husband got part of my retirement (I got none of his) and has access to health care at my employer's expense (though he never contributed). I still work full time as a health professional. Most people who meet me have no idea of what my life has been like. I now have a life free of abuse, but my diagnoses will be with me and my family until we die.

Would you recognize me if you met me? I could be, and others like me could be your sister, your daughter, your mother; or your wife. (Anonymous, Registered Nurse, Staff Educator, survivor of domestic abuse)

Abuse victims not only develop poorer health, they are more likely to practice a variety of injurious and non-compliant health behaviors including: tobacco use, alcohol and/or drug use, risk-taking sexual behaviors, obesity, physical inactivity, lack of seat belt use, lack of helmet use, little or no gun safety practices, decreased self-care, and poor adherence to medication regimes for chronic illnesses.

SURVIVOR STORY—A SUCCESS

A family practice physician was seeing a woman who had a work-related injury that simply would not improve. Because of this, he did an in-depth interview, seeking to identify underlying causative issues. The patient disclosed her history of severe emotional and physical abuse by her husband. He provided her with reassurance, support, encouragement and resources. Ten years later the patient saw this physician in a discount store, approached him and said with great appreciation how thankful she was for his insight and his support. She was no longer in an abusive relationship and attributed her current safe situation to the physician who had known how to ask and, most importantly, how to support his patient.

Health Care Cost

While the full extent of the cost of violence against women to individuals and to society is not fully determined, these figures are unarguably tremendous. Some facts include:

- Direct medical costs for abused women are estimated to be $1.8 billion annually.
- Abuse victims have more hospitalizations, general clinic use, mental health services use and out-of-plan referrals.
- Abused women have a 3.5 fold higher incidence of admission and required hospital care than non-abused women.
- Medical expenses are 2.5 times higher among severely victimized women compared with non-victimized women, On the other hand, data analysis has identified a cost-benefit value to programs that address issues of safe and peaceful lives for women. It was recently reported that the Violence Against Women Act (VAWA) saved $14.8 billion in net averted social costs.

HEALTH CARE PROFESSIONALS AND DOMESTIC ABUSE: WHAT WE MUST DO

Health Care Professionals Must Be Educated

Generally, family violence curricula is incomplete; instruction time is generally minimal, the content and teaching methods vary and subject matter is not well integrated. As a result, health care professionals often enter their professional lives lacking insight into the dynamics of abusive relationships, the issues related to making change in these relationships, and the skills necessary to perform a sensitive and nonjudgmental screening and referral. Many have had no education in this area. Many institutions have incorporated abuse screening requirements without providing staff education. Lack of education is a major barrier to identification, treatment and referral. It is optimal for education to be provided by a team including someone from the health care environment and from a domestic abuse agency.

Schools of medicine and nursing should have advanced curriculum that integrates family violence content throughout. Health care professionals should receive an initial four hours of education. The entire health care team should receive education as well. Initial education should be followed with information to include child abuse, elder abuse, teen violence, cultural sensitivity, childhood sexual abuse and competency building. It is a process, not a "one-stop-shop". Often, those who have not received adequate education have made several, sometimes dangerous, mistakes.

Inappropriate Screening

I have heard countless stories of inadequate or inappropriate screening practices. Consider these examples. A nurse poked her head around the curtain and said to the patient in an offhand, casual manner, "Oh, by the way, you aren't abused by anyone, are you." Two different pregnant women (an advocate for a domestic abuse agency and a family physician who teaches family practice residents to screen for abuse) were screened in the hospital in the presence of their partners. Others have noted that the nurse doing the screening would introduce the subject by saying "Our hospital policy requires me to ask these questions" or "I know this isn't happening to you but I have to ask you: are you being hurt by anyone at home?" Each of these examples illustrates the gross inadequacy of health care professionals' knowledge

base. In these cases, because of their ineffectiveness and potential for jeopardizing the safety of the patient, it would have been better if the nurse had done no screening at all.

Universal Screening

It is important that all patients be screened. Screening should not be selective. Because the health effects of domestic violence result in much more than physical injury, universal screening and interviewing should be an essential component of assessment in health care encounters. It is unrealistic for any health care professional to assume one patient is being abused and another is not. More often than not, it is impossible to tell.

A current medical best-of-practice universally taught and practiced is routine screening for hypertension (high blood pressure). Today, blood pressures are routinely taken in most health care encounters regardless of the reason for the visit. The incidence of high blood pressure in the population is 23 percent. Considering the fact that the lifetime incidence of abuse of women is minimally 25 percent coupled by the significant effect current or past abuse has on health, routine screening is the obvious best of practice recommendation.

SURVIVOR STORY—A CASE FOR UNIVERSAL SCREENING

A middle-aged woman was seen in one of our urgent care clinics for a bee sting. "The clinic routinely screens patients for abuse. The day following her visit, the nurses received the following fax:

"While at the urgent care clinic, one of the nurses was asking a number of probably very normal medical history questions. She also asked a question about domestic abuse. At the time, since my bee sting was totally unrelated to any domestic abuse, I responded by saying no. However that was not a totally true statement. *I am concerned about my living situation and do not feel safe.*

My husband has a violent temper and at times I am afraid for my life. He has raised both hands towards my neck as a choking gesture and says "Do you want to hear a funny sound?" He has said he'd like to whip me with a garden hose in order to "beat the meanness out of me . . . I am involved in a number of volunteer activities and this upsets him very much. He blows up, throws a temper tantrum, slams doors, when I mention another activity. He knew I (volunteered) before we were married and did not object then, in fact he seemed to admire the many things I am able to do. Now however, he is adamant that I retire early from my job and would like me to spend all of my time with him and him alone. I am not allowed to go to the store alone, for instance. He insists on taking me anywhere and everywhere I go.

. . . I am concerned and want to have this on my medical history charts in case anything does happen to me."

This message is more than a request for documentation in the medical record. It is a cry for help. The nursing staff was able to contact this woman, provide reassurance, support and resources.

Develop Partnerships With Local Domestic Abuse Agencies

A key element of success in implementation of screening programs includes developing a working relationship with a local advocacy agency and seeking ways to support advocate visits in the clinical environment. This provides a trusted resource to health care professionals as well as the best case scenarios for victims. We feel the most effective system is to support a health care advocate program where the advocate is employed by the outside agency and works within the health care environment.

Infrastructure and Support of Leadership

Successfully sustained screening practices require a supportive infrastructure. This can include skill-based teaching of screening in employee orientation, evaluating competence and measurements of program compliance and effectiveness. Policies and procedures must be in place to support screening. *Most importantly, without the support of leaders, even the most excellent education and screening programs will encounter sustainability challenges.*

Health Care Settings Should Be Made "Safe Places" To Disclose

Creating a safe place includes having an aware, sensitive staff; educational and community resource information easily available to patients i.e. posters and brochures, and domestic abuse advocates available to see their patients.

UNIVERSAL SCREENING AT ALLINA HOSPITALS & CLINICS

The Process

In 1996, Allina Health System (now Allina Hospitals & Clinics) announced a system-wide focus on violence prevention. Over $1,300,000 was given in violence-prevention research, education and community violence prevention grants. A portion of the grant funds included implementing domestic abuse screening and advocacy referral in Allina's 12 hospitals, over ½ of their 40 clinics and in their obstetric home visiting service. Several educational tools were utilized extensively throughout the system. These include a core curriculum, teaching video and patient educational materials.

The Impact

We have identified a clear and positive relationship between education of health care providers and identification of abuse victims and subsequent referrals to advocates. One example is United Hospital and a nearby clinic, United Family Practice Center, in St. Paul. They also budgeted funding for on-site advocacy services. Prior to education, an occasional victim was identified, one or two a month at the most. After a mandatory education provided to employees beginning with the clinic, Emergency Department and the Birth Center, there was a sharp rise in referrals. These referrals rose steadily and now that the universal screening is implemented hospital-wide have leveled off at 100 per quarter for the last ten quarters. Since the education occurred in 1996, nearly 2000 abuse victims received services from the on-site advocacy service. No one would have received any on-site services prior 1996. Most would not have been identified as abuse victims. Mercy and Unity Hospitals in the suburban Minneapolis area experienced a significant rise in referrals after a major launching of screening and education in 1995–96. Throughout ensuing years through 1999, referrals consistently averaged around 100 per quarter. During that time the hospitals budget supported on-site advocacy. In the last two years, program changes, decreased leadership support and budget cuts at these two hospitals have resulted in elimination of education funding, support for on-site advocacy and a decrease in leadership support As a result, the referral rate decreased by nearly 50 percent. Some leaders have now identified this as a problem and are working on solutions.

By making patient educational materials available to the public, literally thousands of community members have been provided with basic information educating them about unhealthy, violent relationships and telling them how to get help. It is not uncommon that half of the community does not know how to access domestic violence services.

Another significant benefit is creation of culture changes within the work place. Creating a "safe place" provides support not only to our patients but to our employees. Respondents to a 1996 health questionnaire mailed to new members by Medica, an insurance provider for Allina, revealed that 22 percent of them answered yes to the question "Have you ever been hit, kicked, pushed, or otherwise hurt or mistreated by someone important to you?" In cultures of "safe places" employees who are being hurt feel supported and encouraged to seek help.

SURVIVOR STORY—STANDING BESIDE YOU

"A few months ago, my husband broke one of my fingers. I came in to the emergency department for treatment and told them I fell. I was so hurt and confused that someone I loved could treat me so horribly. I was too embarrassed to tell them what really happened. Quite a few of my coworkers jokingly asked, "What happened to your finger? You and your husband been fighting?' I wanted to say, yes, can you help me? But just like my coworkers, I couldn't believe that I, an emergency nurse who sees abused women, helps abused women . . . could be an abused woman."

Research is needed to establish a basis for practice. However, unless professionals are well educated on the subject, have supportive policies in place, have an ongoing evaluation of their program and have leadership support, assessment and intervention will be ineffective at best and potentially dangerous at worst.

WE BELIEVE WHAT WE ARE DOING CAN SAVE LIVES

Survivor Story—No one Asked

A survivor of domestic abuse shared her health care experience with me. She had sustained a serious head injury when her husband repeatedly smashed her head into the cement of their driveway. In desperate fear for her life, she went to a local Emergency Department to have her injuries evaluated. She disclosed her feelings about what she wanted from the health care professionals in that hospital. "I

thought I was dying. I felt as though I was floating above my body. If someone had asked me if I was being hurt by someone in my life, *I would have spilled my guts. But no one asked me.* And I went back home with my abuser."

Senator MIKULSKI. Dr. Gellhaus?

Dr. GELLHAUS. Thank you very much.

Good afternoon, distinguished members of the committee. I am Dr. Tom Gellhaus. I appear before you on behalf of the American College of Obstetricians and Gynecologists and as a practicing physician from Iowa.

ACOG represents 44,000 physicians dedicated to improving women's health care. I am honored to be here today at this important hearing.

My comments focus on safe motherhood—a woman's ability to have a safe and healthy pregnancy, delivery, and postpartum period free of health complications. But I should add that the full range of issues explored by this hearing is important to ACOG members.

Approximately 4 million Americans become pregnant each year, and more than 10,000 give birth each day. Most women can count on having a healthy pregnancy. However, every pregnancy faces risks, and every pregnant woman can develop sudden life-threatening complications that require high-quality obstetric care.

Each year in the United States, 30 percent of pregnant women have pregnancy-related complications before, during, and after delivery that may lead to long-term health problems. Approximately 1,000 of these women die each year; that is two to three deaths each and every day. Over half of these deaths could be prevented through improved health care access, improved quality of care, and changes in maternal health and lifestyle habits.

The importance of legislation to ensure a safe pregnancy for all women in the United States must not be underestimated, and ACOG fully supports these efforts. Unfortunately, there is still much that we do not know about pregnancy and its complications. Why do some women have life-threatening complications? Why do some women survive and others do not? What causes these complications? How do factors of race, age, and education level affect maternal health?

Reducing maternal morbidity through coordinated Federal action is essential. ACOG has a long history of collaborating with the Centers for Disease Control and Prevention on the production of State-level educational materials on mortality reviews.

We also strongly support grants to assist States in their transition to a national standard of tracking pregnancy-related deaths. Collaborative partnerships among Government agencies, physicians, universities, and community groups are the first step to systematic change.

Increased funding for research in maternal health could shed light on a breadth of issues that could save women's lives. Pre-term labor and hypertension in pregnancy are two of the leading pregnancy complications, yet little is known about the causes of these conditions or possible preventive treatments.

We know very little on effective intervention against maternal smoking, alcohol, and drug use. We need more information on the

causes and ways to prevent postpartum depression so we can diagnose and treat our patients appropriately.

Very alarming is the disparity in maternal mortality and morbidity in relation to race and ethnicity. Why are African American women four times more likely than Caucasian women to die from pregnancy-related causes? How do we protect minority women and low-income women who are already at increased risk for chronic disease?

Family planning is preventive health care. Without contraception, the average woman could become pregnant more than 12 times over her life—a prospect too risky for most women. Family planning is critical to improved maternal health by allowing women to space the number and timing of their pregnancies.

Women who conceive within 6 months following childbirth are 70 percent more likely to have their membranes rupture prematurely. Pregnancy can be life-threatening for women with serious medical conditions such as heart disease, diabetes, lupus, and hypertension. For these women, family planning can be life-saving. It can help them prevent pregnancy altogether, or it can help these women postpone pregnancy until they are healthy enough to support a pregnancy.

As a practicing physician, I applaud your effort to increase knowledge and data on the effects of drugs on pregnant women. Pregnant women become ill just as we all do. The difference is that we do not know how even some of the most commonly prescribed medications affect the pregnant woman or the developing fetus. Currently, approximately two-thirds fall into FDA's Category C, which is considered potentially unsafe to use during pregnancy, either because no studies demonstrating their safety for pregnant women are available or because they have been shown to harm animal fetuses.

Many women who become pregnant discontinue medications during pregnancy—for example, high blood pressure medicines and cholesterol-lowering drugs. Yet women who suffer from chronic diseases like epilepsy, HIV, or depression do not have the luxury of going without these medications for 9 months. Indeed, pregnancy can actually exacerbate conditions like asthma and high blood pressure, making it even more critical for physicians to make informed decisions about the treatment of their pregnant patients.

Physicians make the best decisions we can with the information available. We are trained to make medical decisions based on professional judgment, yet I cannot overstate the need for more research and data in this area. Pregnant women are the last population for which we do not have drug information.

Thank you for giving me this opportunity to testify on behalf of my patients and ACOG on this important subject of safe motherhood. It is time to move forward with new research, new interventions, and new cooperation to ensure that women and their doctors have the best information available to make informed decisions about their lives and their pregnancies.

I thank the committee for holding this hearing today and for allowing me the opportunity to testify. This legislation is critical to the health of our Nation's women.

Thank you.

[The prepared statement of Dr. Gellhaus follows:]

PREPARED STATEMENT OF THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

Good afternoon Mr. Chairman and distinguished members of the committee. I am Dr. Thomas Gellhaus. I appear before you on behalf of the American College of Obstetricians and Gynecologists (ACOG). I am currently in practice at Obstetrics and Gynecology Specialists, PC, in Davenport, Iowa, and teach in the Department of Obstetrics and Gynecology at the University of Iowa's College of Medicine.

I am honored to be here today, and on behalf of ACOG, we couldn't be more pleased with the attention and commitment to women's health consistently demonstrated by members of this committee and by the scheduling of this important hearing. The American College of Obstetricians and Gynecologists (ACOG) represents 44,000 physicians dedicated to improving women's health care. Ninety-five percent of board certified obstetricians and gynecologists in the U.S. are members of ACOG.

I have been asked to focus my comments specifically on the issue of "safe motherhood" and issues related to pregnancy and women's health, but I should add that the full range of issues explored by this hearing is important to ACOG members. As Ob-Gyns we not only care for and treat patients during their pregnancies but throughout their lifetime. We believe that improving women's health is a vital investment.

Safe motherhood is a necessarily broad term but in the context of this discussion my remarks will narrow the focus of safe motherhood to refer to a woman's ability to have a safe and healthy pregnancy, delivery, and postpartum period free of life or health threatening complications.

Approximately 4 million American women become pregnant each year, and more than 10,000 give birth each day. Most women can count on having a healthy pregnancy. However, every pregnancy faces risks: every pregnant woman—regardless of income or education—can develop sudden, life-threatening complications that require high quality obstetric care. Although rates of maternal morbidity and mortality decreased dramatically in the U.S. between 1950 and 1990, the last two decades have seen little progress.

Each year in the U.S., 30 percent of pregnant women have pregnancy-related complications before, during, or after delivery that often lead to long-term health problems. Approximately 1,000 of these women die each year. Over half of pregnancy-related deaths could be prevented through improved health care access, improved quality of care, and changes in maternal health and lifestyle habits.

The importance of legislation to help ensure a safe pregnancy for all women in the United States must not be underestimated and ACOG fully supports these efforts. Unfortunately there is still much we do not know about pregnancy and its complications. Why do some women have life-threatening complications? Why do some women survive them and others do not? Why are there racial and ethnic disparities in maternal morbidity and mortality? How do the factors of age, marital status, and education levels affect maternal health? What causes certain complications and how can we treat them?

REDUCING MATERNAL MORBIDITY THROUGH COORDINATED FEDERAL ACTION

ACOG has a long history of collaborating with the Centers for Disease Control and Prevention (CDC) on the development and publication of educational materials regarding mortality reviews at the State level, and we have collaborated with the American Academy of Pediatrics, March of Dimes, and others to promote healthy pregnancy. We appreciate the efforts to broaden this focus to include morbidity and to take it to the next level by formalizing collaborative partnerships among government agencies, physicians, and community groups. We strongly support grants to assist States' transition to a national standard of tracking pregnancy-related deaths through certificates of death. States can improve identification of cases, review of pregnancy-related deaths, and interpretation of the findings. These efforts will go a long way toward implementing systemic change in improving pregnancy outcomes.

It is essential that we seek to understand what trends and differences between populations may play a role in maternal mortality. Through community partnerships we can provide information and direction for public health efforts to improve women's health. For example, ectopic pregnancy, when the fetus develops in the Fallopian tube instead of the uterus, is the leading cause of death during the first trimester. While collecting data on these pregnancies is imperative, ectopic pregnancies are currently the only maternal complication regularly monitored in the

U.S. We must work together to broaden the scope of the data available for other common complications.

INCREASED FUNDING FOR RESEARCH

We are pleased with the recognition for increased funding for research in every aspect of safe motherhood. Each day in the U.S. between two and three women die of pregnancy related causes. And each year at least 30 percent of pregnant women in the United States have a pregnancy-related complication before, during, or after delivery. These complications can cause long-term health problems even when they do not result in death. According to the CDC, childbirth remains the most common reason for hospitalization in the United States, and pregnancies with complications lead to more costly hospitalizations. A commitment to research in maternal health could shed light on a breadth of issues that could save women's lives. Pre-term labor is one of the leading and most profound complications affecting pregnancy, yet little is known about causation of this condition or possible preventive treatments. Likewise, pre-eclampsia, pregnancy-induced high blood pressure and swelling, is a very common complication, and there is the same paucity of research on how we can prevent it. Studies of maternal behavioral practices could lead physicians to new interventions against alcohol, cigarette, and drug use during pregnancy. More information on the causes and the diagnoses of postpartum depression could educate physicians on appropriate preventive and follow-up care for at risk women. Perhaps one of the most alarming trends to address is the disparity in maternal mortality and morbidity in relation to race and ethnicity. African American women are four times more likely than Caucasian women to die from pregnancy-related causes. Hispanic women are 1.7 times more likely to die than their Caucasian counterparts. Racial and ethnic minority women, as well as women with low incomes, are already at increased risk to develop chronic disease. This risk, compounded with high risk for poor pregnancy outcomes, creates an inequality that we can no longer ignore.

FAMILY PLANNING AS PREVENTIVE HEALTH

Biologically, most women can become pregnant for nearly forty years of their lives. Without contraception, the average women could become pregnant more than twelve times, a prospect that would carry an unnecessary amount of risk for most women.

Family planning is critical to improved maternal health by allowing women to space the number and timing of their pregnancies. Studies show that women who conceive within six months following childbirth increase the risk of pregnancy complications. According to the November 2000 *British Medical Journal*, "women who became pregnant less than six months after their previous pregnancy were 70 percent more likely to have membranes rupture prematurely and had a 30 percent higher risk of other complications."

Pregnancy can be life threatening for women with serious medical conditions such as heart disease, diabetes, lupus, and high blood pressure. For these women, family planning can be life saving. It can help them prevent pregnancy altogether, or it can help these women postpone pregnancy until they are healthy enough to support a pregnancy.

One half of all pregnancies in the U.S. are unintended. Effective contraception can give women suffering from chronic disease more autonomy over their own health decisions. These women have the chance for better health outcomes, whether they choose to become pregnant or not.

PREGNANCY AND DRUG INTERACTION

As a practicing physician, I applaud your effort to increase knowledge and data on the effects of drugs on pregnant women. Pregnant women get sick just like we all do. The difference is that for even the most commonly prescribed medications, there is very little information available to help doctors know what the best dose of a particular medicine is for pregnant women and how that medication may affect the developing fetus.

Currently, approximately ⅔ of all drugs fall into Category C, under FDA guidelines. Drugs in this category are considered potentially unsafe to use during pregnancy, either because no studies demonstrating their safety for pregnant women are available or because they have been shown to harm animal fetuses. In prescribing medications to my patients, I can only make my best judgment based on the little data that is available.

Many women who become pregnant discontinue their medications during pregnancy, for example allergy medications or dermatological drugs. Yet women who suffer from chronic diseases like epilepsy, HIV, or depression do not have the luxury

of going without treatment for nine months. Indeed, pregnancy actually can exacerbate conditions like asthma and high blood pressure, making it even more critical for the physician to make informed decisions about the treatment of their pregnant patients. In addition to general questions about safety, almost no information is available to help doctors know what the best dose of a particular medicine is for pregnant women. Changes in the body's physiology during pregnancy have the potential to require that doses be increased or decreased.

Physicians make the best decisions we can with the information available. We are trained to make medical decisions based on professional judgment. Yet, I cannot overstate the need for more research and data in this area. Pregnant women are the last population for which we don't have drug information.

CONCLUSION

Thank you for giving me the opportunity to testify on behalf of my patients and ACOG on this important subject of safe motherhood. The goals of the legislation being introduced today, with the support of so many other groups committed to women's health, are laudable and overdue. Together, physicians, advocates, and government agencies can make a difference in maternal mortality and morbidity rates.

Despite our best efforts to decrease pregnancy-related complications, we have reached a plateau in the past decade. It is time to move forward with new research, new interventions, and new cooperation to ensure that women and their doctors have the best information available to make informed decisions about their lives and their pregnancies.

I thank the Chair and this committee for holding this hearing today and for allowing me the opportunity to testify. This legislation is critical to the health of our nation's women.

Senator MIKULSKI. Thank you, Dr. Gelhaus.

Senator Harkin did want to be here, but he is in the Agriculture conference fighting for Iowa, so he sends his apologies.

Dr. GELLHAUS. Thank you.

[The prepared statement of Senator Harkin follows:]

PREPARED STATEMENT OF SENATOR HARKIN

I want to recognize Senator Mikulski for her leadership on issues related to women's health.

Most recently, Senator Mikulski and I held a joint hearing on the efficacy and importance of mammography. We have also worked together to involve women in FDA clinical trials so that drugs and devices are tested as safe and effective for both men AND women. I thank her for her leadership on these and so many other women's health issues and I am also proud of our work together on women's health. I look forward to continue our successful collaboration in the future.

Today's hearing will address the broad range of health issues affecting women. In addition to testimony from the Administration, we also hear from researchers and health providers about critical issues including pregnancy, health screening and prevention, and domestic violence.

In addition to the direct testimony we will hear from the witnesses, a number of individuals and organizations have submitted written testimony on these and other important issues.

Today, I would like to focus my remarks on two of the critical areas affecting women's health—early detection screenings for low-income and needed improvements in maternal health and safe motherhood.

In the area of early detection, Senator Frist and I have introduced the WISEWOMAN Act, which would expand access to health

care screening programs for low-income woman throughout the country.

The existing WISEWOMAN program, which is modeled after the Breast and Cervical Cancer Screening Program, provides more comprehensive health care screenings to women in Massachusetts, Arizona, and North Carolina. The time has come to expand this successful program so that every woman has access to early detection screenings for diseases such as heart disease, diabetes, and osteoporosis. WISEWOMAN will save lives through early detection and save health care dollars by helping America's women lead healthier lives.

We must also do more in the area of safe motherhood.

Over the last decade there has been a significant recognition of the importance and increase in funding of women's health research, including the establishment of Offices of Women's Health throughout various government agencies. Women's health issues and women, as participants, are now routinely included in research studies.

Despite this progress, many gaps still exist. In particular, there is a troubling lack of research on pregnancy-related health issues. Too often we take pregnancy for granted; we do not view pregnancy as a woman's health issue with short and long term health consequences.

Safe motherhood is a woman's ability to have a safe and healthy pregnancy and delivery. Of the four million women who give birth in the U.S. each year, over one-third—or one out of every three—have a pregnancy-related complication before, during, or after delivery. These complications may cause long-term health problems or even death. Unfortunately, the causes and treatments of pregnancy-related complications are largely unknown and understudied.

In fact, the U.S. ranks only 20th in maternal mortality rates out of 49 developed countries—that is barely better than the 50th percentile, behind Cyprus, Singapore and Malta. Every day, two to three women die from pregnancy related complications. And despite the fact that maternal mortality was targeted in 1987 as part of Healthy People 2000, the maternal mortality rate in this country has not decreased in twenty years.

The scariest part of this problem is we can't answer the most basic questions—what causes the complications, what can we do to prevent them, and how can we treat them?

One example of this problem is pre-eclampsia, or high blood pressure. Yes, we know some indicators that place some women at greater risk than others for this complication. And yes, we know some steps that can be taken to reduce a women's risk. But we know shamefully little, with the exception of inducing labor, of how to really prevent or treat this problem. Yet five percent of all pregnancies are affected by this complication, which can cause blindness or even death and there has been a 40 percent increase in the incidence of pre-eclampsia over the last 10 years.

Likewise, we know almost nothing about which prescription drugs are safe for the fetus and effective for the mother. Most prescription drugs women take during pregnancy are necessary to maintain health. But only one percent of FDA approved drugs have

been shown in controlled studies to show no risk to pregnant women and their babies. And 80 percent of FDA approved drugs lack adequate scientific evidence about use in pregnancy. That means that pregnant women are essentially forced to take these medications with little or no knowledge about their impact on the fetus.

Of course, we don't want pregnant women placed at risk by putting them in early stage clinical trials. But the fact is that pregnant women with chronic diseases, such as diabetes, asthma, or epilepsy, need to take medication to maintain their health and support the growth of the fetus. And even pregnant women who don't have chronic health conditions need access to safe and effective prescription drugs.

And while people in Washington tend to throw around statistics to make a point, it is important to remember that behind each of these statistics is a real person and family. And yesterday, I had the opportunity to talk to a group of moms from my State of Iowa. Without exception, these moms talked about their frustration with a health care system that continues to fail to meet some of the most basic needs of pregnant women. They all rely on a group called Sidelines, that provides support and guidance to pregnant women on bed rest. While it is great that a group like Sidelines is there for our mom's, sisters, and daughters, it is shameful that there isn't more accurate and more widely available information to women and their providers.

That is why earlier today, I, along with some of my colleagues, introduced the Safe Motherhood Act for Research and Treatment, or, SMART Mom Act. The SMART Mom Act will address these concerns by:

- increasing research and data collection to learn how to prevent, treat, and cure pregnancy related complications;
- providing comprehensive information to pregnant women, practitioners, and the public; and,
- improving information about medication and medical device use for pregnant women.

Pregnancy is a natural and wonderful occurrence in a woman's life. The SMART Mom Act takes a critical step towards ensuring pregnancies and healthy outcomes for America's women.

These are just two of the many important issues that will be addressed at today's hearing. I look forward to hearing from my colleagues on the subcommittee and from our distinguished witnesses.

Senator MIKULSKI. To the panelists and also to Dr. Slater and Dr. Marks, first, we want to thank you for being you. We want to thank you for what you are doing each and every day in every way to make the lives of women and your patients better.

We want to particularly thank you for your testimony today. It has given us a lot to think about and in many ways, a real action plan to pursue.

We are going to have some questions, but we will get back to you in writing. We so regret—I cannot tell you how much we regret—that we have to adjourn this committee for the 5 to 12 votes on the energy bill. So we offer our very sincere apologies, but it is in no way due to lack of interest.

We again want to express our deep appreciation, and we are going to be seeing many of you again.

Senator WELLSTONE. Mr. Chairman, could I just echo what you said, and also as a point of personal privilege, thank Phyliss Greenberger who is here for all of her work and leadership.

This was great testimony. Thank you.

Senator MIKULSKI. This committee stands adjourned.

[Additional material follows].

ADDITIONAL MATERIAL

RESPONSE TO QUESTIONS OF SENATOR HARKIN FROM EVE SLATER, M.D.

Question 1. It has come to my attention that the Administration is planning to move the Office of Women's Health from their current location in Washington, DC to offices in Rockville, MD. How does this move reflect upon the Administration's commitment and interest in continuing and expanding upon the initiatives you described in your testimony?

Answer 1. No decision has yet been made with regard to relocating the Office on Women's Health. The Department is still considering its options, consistent with Secretary Thompson's initiative aimed at greater departmental efficiency and effectiveness. We do not anticipate any change in the impact or visibility of the office.

In fact, the Secretary and the President have made women's health one of the top priorities of their health agenda. As a demonstration of this Administration's commitment, the fiscal year 2002 budget included a $9+ million increase for women's health and the President has proposed an additional $2+ million for fiscal year 2003.

Question 2. As you know, I introduced a bill today with Senators Kennedy and Mikulski which will increase research on pregnancy-related illness and death, address the racial and ethnic disparities in maternal health and mortality, and give pregnant women more information about the safety and efficacy of FDA approved medications during pregnancy. I have two questions about this bill.

Question 2, subpart 1. First, the United States has one of the highest maternal mortality rates in the industrialized world, and as I mentioned in my opening statement, those rates have not improved in 20 years. However, perinatal diseases rank as the second lowest NIH-funded group of diseases when comparisons take into account disability adjusted life years lost due to each disease. Given that ⅓ of women will experience a complication during pregnancy, why hasn't pregnancy related complications been a higher priority in the past, and do you believe that the time has come to invest more resources in this field of research?

Answer 2.1. Research is being supported by NIH on both "normal" as well as higher risk pregnancies. In order to increase our understanding of the causes of and potential therapies for disorders and other problems associated with pregnancy, we must first understand what constitutes and contributes to a normal pregnancy. At the National Institute of Child Health and Human Development (NICHD), for example, $138,215,974 was spent overall on pregnancy related research in fiscal year 2001, including extramural and intramural, human and animal, basic and clinical research. Of this total, in fiscal year 2001 NICHD expended ($113,072,685) over 80 percent in support of research on pregnancy-related problems, including high-risk pregnancy, fetal pathophysiology, premature labor and birth, and disorders of pregnancy such as gestational diabetes, pre-eclampsia and spontaneous abortion. About half of this funding came through the Pregnancy and Perinatology Branch in the Institute's Center for Research on Mothers and Children, and the other half was spread out among several other branches.

Modern obstetrical management, especially the management of high-risk pregnancies, has in some instances adopted principles of care and employed pharmaceuticals and methodologies that have not been rigorously tested using controlled observations. Often, procedures enthusiastically embraced at first are modified or replaced later after extensive experience has failed to support their usefulness or shown unexpected consequences. Regional differences have further complicated the field.

Specifically, in an attempt to respond to the need for well-designed clinical trials in maternal-fetal medicine, NICHD established a Network of Maternal-Fetal Medicine Units in 1986. The Network Steering Committee, which consists of representatives from each clinical center, NICHD staff, and data coordinating center staff, selects priority areas for study. The Data Monitoring and Safety Committee advises NICHD on research design issues, data quality and analysis, and ethical and human subject protection aspects of the trial protocols. More than 24 randomized clinical trials, cohort studies and registries have been completed or are in progress, including on questions relating to post-term pregnancy, predictors and management of preterm labor, and prevention of pre-eclampsia. Others are planned for the near future.

The National Institute of Nursing Research (NINR) is also committed to supporting research that focuses on maximizing the health of pregnant minority women and their developing offspring with a particular focus on eliminating health disparities. A currently published initiative, Low Birth Weight in Minority Populations, solicits

research to expand our understanding of the underlying mechanisms that contribute to the ethnic variations in low birth weight (LBW) and strategies for prevention.

In addition, NINR is currently funding several promising studies related to pregnancy complications. Pre-eclampsia affects nearly 1 in 20 pregnancies and is the leading cause of maternal deaths worldwide. Two studies are underway to examine the effects of exercise on preventing the onset or the recurrence of pre-eclampsia. Another area of investigation is gestational diabetes. Diabetes is a major risk factor during pregnancy, and African American women have higher rates of diabetes, more maternal complications, and a greater incidence of low birth weight. Researchers are examining the barriers to treatment adherence among African American women with gestational diabetes. Another researcher is testing a web-based outreach program for pregnant African American women. Other important areas of ongoing research related to pregnancy complications include smoking cessation, drug abuse, domestic violence, and perinatal HIV transmission.

The Office of Research on Women's Health (ORWH) serves as the focal point for women's health research at NIH and has developed priorities for research based upon its Agenda for Research on Women's Health for the 21st Century. ORWH has identified, as a priority, new and expanded research on pregnancy related issues. These include research into the effects of infections (including oral infections and inflammation) on adverse pregnancy outcomes; gestational diabetes and other disease manifestations and treatments during pregnancy; prevention, diagnosis, and treatment of pregnancy complications including fetal loss, low-birth weight infants, and the development of neural tube defects; and the impact of pregnancy and lactation on the pharmacokinetics, pharmacodynamics, drug efficacy and side effects in pregnant women, including their genetic, molecular and cellular bases.

The NIH Office of Research on Women's Health (ORWH) supports a number of research grants that focus on pregnancy and/or pregnancy outcomes in collaboration with other NIH institutes and centers, including the National Institute of Child Health and Development (NICHD), the National Institute of Dental and Craniofacial Research (NIDCR), the National Institute of Diabetes, and Digestive and Kidney Diseases (NIDDK), and the National Institute on Alcohol Abuse and Alcoholism (NIAAA).

For example, in fiscal year 2001, the ORWH funded with NIDCR an innovative research project evaluating whether maternal peridontitis is a risk factor for adverse pregnancy outcomes. A total of 6,000 pregnant women were enrolled in the parent study, a number sufficient to permit detailed investigation as to whether maternal infection during pregnancy leads to preterm delivery. Peridontal infection, a highly prevalent condition that can be controlled, can serve as a reservoir of gram-negative anaerobic organisms. Certain mediators can target the placental membranes via systemic circulation, thereby leading to preterm delivery or fetal growth restriction. Increased understanding of these relationships can improve the well-being of mothers and infants.

During both fiscal year 2000 and fiscal year 2001, ORWH co-funded several grants in the area of obesity and pregnancy with NIDDK. One study focused on slowing the accumulation of weight in women of child-bearing age and recruited a group of women from lower income and rural locations. A second study targeted African-American women and used Internet-based interventions to prevent pregnancy-related obesity. The Internet-based interventions were used in face-to-face group sessions that allowed for more intensive behavioral feedback.

Neuromuscular injury and recovery after vaginal delivery was studied in a group of Caucasian, African-American and Hispanic women who were in their third trimester of pregnancy in an NICHD and ORWH supported investigation. Specific labor events associated with neuromuscular maternal injury were studied longitudinally in relation to race/ethnicity. Outcomes included symptoms of prolapse and incontinence, as well as their pelvic neuromuscular function over time. By studying this problem longitudinally, an increased understanding will be obtained of the neuropathic role that delivery plays in the development of pelvic floor disorders.

Question 2, subpart 2. And second, the bill also will also improve our understanding of the effects of prescription medications on pregnant women. Women with chronic illnesses, such as epilepsy or asthma, or who have even minor health problems, such as a sinus infection, currently must make choices about taking medication without sufficient information about the effect of the drug on the future health of their child. I understand that the FDA and NIH are undertaking several initiatives in this area. Can you expand on what is currently being done within the Department to address the lack of information on drug safety for pregnant women and whether you support the approach taken in our bill?

Answer 2.2. We know that the metabolism of women changes during pregnancy. What we do not know - despite the fact that pregnant women with chronic conditions regularly continue their medications—is how much those changes impact the effectiveness of drugs for different conditions, nor what dosage may be safely taken by the pregnant woman without negatively affecting her developing child. The NIH, including NICHD and ORWH, and FDA explored this question in December 2000 at a groundbreaking conference that focused largely on the need for information about drugs used by pregnant women with chronic health conditions. Working in conjunction with the FDA since that time, NICHD has planned a major new initiative to test drugs frequently used by pregnant women who have conditions such as epilepsy, asthma, hypertension and diabetes. The NICHD plans to conduct physiological studies to explore the differences in metabolism during pregnancy, along with trials for dosage and effectiveness for the most commonly used drugs through a network of sites around the country.

ORWH has also cosponsored with the CDC a workshop on Concepts and Strategies to Actively Monitor the Risk of Medication in Pregnancy: Enhancing Post-Marketing Surveillance.

The Food and Drug Administration (FDA) works with drug sponsors at all stages of a drug's development to better understand how a drug will affect different populations once it is marketed. The Agency believes it must identify important information about a drug, such as dosages for different age groups, genders, and subgroups, and to use that information to refine labeling information, patient selection, and dose selection.

Research on Medications Used in Pregnancy

Most pharmaceutical products are not studied in pregnant women, yet pregnancy may alter the safety and efficacy of prescription medications. Rational prescribing for the pregnant patient must attempt to ensure the greatest likelihood of clinical benefit for the mother and the safest exposure for her developing baby. This can only be achieved when adequate pharmacokinetic and pharmacodynamic information throughout the pregnancy is available.

In fiscal year 2001, FDA Office of Women's Health funded research on prescription medications commonly used to treat high blood pressure (hypertension) during pregnancy to determine doses that provide the greatest benefit and least risk for the mother and her baby. The contracted studies are evaluating the safety and effectiveness of medications already being used by the pregnant women enrolled in the study. The studies are following all ethical and patient protection regulations. The studies are intended to demonstrate that this type of study can, and should be done for medications widely used during pregnancy. The studies are being conducted at two DHHS National Centers of Excellence in Women's Health.

In fiscal year 2002, FDA Office of Women's Health and the Center for Drug Evaluation and Research (CDER) plans to fund research to use large automated health plan databases as well as clinical studies to evaluate maternal safety and/or fetal outcomes in women exposed to certain prescription medications during pregnancy with a focus on medications used for treatment of bioterrorism agents. Large automated health plan databases containing prescription drug use and health outcome information will provide timely monitoring of maternal and fetal safety.

Pregnancy Registry Website

The FDA Office of Women's Health will launch a new website shortly to provide information for women taking medications during pregnancy and lactation.

Current Guidances

In addition to proposing rulemaking to improve pregnancy and lactation labeling, and funding research to determine the best way to conduct studies in pregnant and lactating women, the agency has published the following guidances to help improve the quantity and quality of data available for inclusion in this section of the labeling:

1) Guidance for Reviewers: Evaluating Human Pregnancy Outcome Data. Draft published June 1999.

2) Guidance for Reviewers: Integration of Study Results to Assess Concerns about Human Reproductive and Developmental Toxicities. Draft published November 2001.

3) Guidance for Industry: Establishing Pregnancy Registries. Draft published June 1999.

4) Guidance for Industry: Non-clinical and Clinical Studies on the Transfer of Drugs and Biological Products into Breast Milk. In process.

5) Guidance for Industry: General Considerations for Pharmacokinetic Studies in Pregnant Patients: Study Design, Data Analysis, and Impact on Dosing and Labeling.
6) Guidance for Industry: Risk Management Approaches for Known or Suspected Human Teratogens.

PREPARED STATEMENT OF MICHAEL M. FAENZA

On behalf of the National Mental Health Association, and our 340 affiliates nationwide, representing the over 54 million individuals with mental illness in this country, I would like to commend Senators John Edwards and Patty Murray for introducing the Women in Trauma Act of 2002 (S. 2204). This legislation deals with one of the most tragic deficiencies in our mental health system-the widespread failure to address the traumatic incidents that are part of the histories of many women with mental health and/or substance abuse disorders.

Research indicates that 50 to 70 percent of women treated in psychiatric settings have histories of trauma including sexual or physical abuse or both. According to one recent study, ninety-seven percent of homeless women with mental illness have experienced severe physical and/or sexual abuse. Trauma exposure can directly cause mental disorders, and even for those whose illness predates exposure to trauma, that trauma can worsen the course and overall impact of mental illness and substance abuse. Battered and abused women suffer serious mental health consequences from the trauma inflicted upon them, including higher levels of depression, drug and alcohol abuse, and suicide attempts. Many studies have shown that childhood sexual abuse is a high risk factor for mental health and substance abuse problems later in life. Women abused as children are four times more at risk for major depression and they are significantly more likely to develop eating disorders and chronic posttraumatic stress disorder. Research has also shown that a high percentage of women with alcoholism suffered abuse as children. Unresolved trauma-related symptoms can contribute to relapse into using alcohol or other drugs to cope with the long-term effects of trauma.

However, mental health and substance abuse services for women rarely address the significant possibility that trauma, including physical abuse, sexual abuse, rape, or domestic battery, may have played a role in instigating, aggravating, and/or prolonging a woman's mental health or substance abuse disorder. There is widespread failure in the mental health and substance abuse systems to assess, diagnose, and address the complexities added to the treatment process by the effects of traumatic experiences. There is an urgent need to evaluate treatment strategies and models and improve treatment for female victims of violence with addictive and mental health disorders. The impact of violence on women with mental health and/or substance abuse disorders must be addressed.

The Women in Trauma Act would establish an important milestone in authorizing funding to conduct research to expand our knowledge regarding effective treatment for mental health and substance abuse disorders in women who have experienced physical or sexual abuse or other types of trauma.

In addition, this bill would help communities develop and implement comprehensive community-based mental health and substance abuse services for women with histories of trauma. These services are to be provided through cross-disciplinary systems of care that address mental health, substance abuse, and other needs in an integrated and trauma-informed manner. Dysfunctional behaviors and/or symptoms in women impacted by violence often originate as coping responses to trauma. Moreover, women who have experienced repeated trauma in childhood often lack adult coping skills because they were deprived of the opportunity to develop them. The mental health and substance abuse interventions and support services that would be funded through the Edwards/Murray bill would help participants in this program overcome the complex and insidious influence of trauma and violence in their lives.

Many women who have been repeatedly abused feel powerless and unable to protect themselves, often leading to isolation from others. Under this measure, community-based systems of care would provide women impacted by violence with the treatment and support systems they need to take control over their lives and overcome their mental health or substance abuse problems.

A critically important component of the Women in Trauma Act is the requirement that grantees involve those women participating in a grant site's treatment program in all phases of service design and delivery. This provision in the bill recognizes the importance to these women of regaining control over their lives and confidence in their own abilities. Moreover, the perspective of these women on how treatment and

support services should be structured would be essential to designing effective programs.

Women suffering from traumatic experiences and related mental health and/or substance abuse disorders often need services that go beyond treatment, including housing, child care, and medical and employment assistance. To address the lack of coordination and barriers to accessing necessary services, entities awarded grants under the Edwards/Murray bill, would be required to implement an integrated, systems-of-care approach that incorporates cross-agency collaboration to improve access to the services and supports many of these women need to achieve empowerment and recovery.

This bill also would improve the capacity of other types of service providers, including rape and domestic violence programs, hospital emergency rooms, appropriate branches of the criminal justice system, to recognize and address the trauma-based underpinnings of mental health and/or substance abuse disorders in many women.

In addition, the Edwards/Murray bill recognizes the need to reach out to diverse communities. Such outreach serves two purposes. It is critical to ensuring effective treatment for members of diverse communities through recognition and accommodation of cultural differences. Such outreach is also vital to improving awareness and access among diverse groups to treatment programs that recognize the importance of addressing violence and trauma as a way to improve mental health and substance abuse treatment for many women.

Recognizing that access to childcare is a primary barrier to treatment for many women, the Women in Trauma legislation would authorize the use of grant funds to provide childcare, either directly or through an off-site, licensed child care provider, to women receiving treatment through a grantee's treatment program.

This bill is a crucial first step in remedying a grave shortcoming of current practice in mental health and substance abuse treatment for many women. The importance of modifying treatment practices to take into account the histories of trauma experienced by a significant percentage of women with mental health and/or substance abuse disorders has been ignored for far too long. By funding community-based services and research to address the profound impact of trauma and violence on substance abuse and mental health disorders in women, the Women in Trauma Act takes great strides to address this very important and long overlooked women's health issue. I applaud Senators Edwards and Murray for their efforts and their leadership.

PREPARED STATEMENT OF KIM HOFFMAN

Mr. Chairman, my name is Kim Hoffman. I am a breast implant recipient from Missouri.

As the watchdog of public safety for food, drugs and medical devices, the FDA has failed specifically in its duties, by allowing a medical device with high complication rates to be marketed to American women by companies with dubious manufacturing practices.

Like thousands of other women, I experienced numerous debilitating problems immediately after receiving my textured, silicone breast implants, manufactured by Mentor Corporation, in 1995. To receive silicone implants after the moratorium in 1992, I was required to participate in a clinical study. Because data collected in this study could effect FDA's decision as to whether the agency should approve the wide spread availability of the product, I recognized the importance of accurately documenting my problems and including them in the study.

I reported my problems to my surgeon. He ignored me. I obtained a copy of the study protocol and realized a number of study rules had been violated. I reported the violations, and my physical problems to the manufacturer, who was the sponsor of the study and to the FDA; again, I was ignored. After numerous attempts to report my complications as a study participant, I received a form from my file at the manufacturer; it read, "patient has no complaint."

Astonished by the apathetic responses I'd received, and being from the show me State, I began my own investigation. I interviewed several other study participants and found problems with their cases as well. I was able to talk to people who worked for the manufacturers and even a couple of industry whistle-blowers. From them I learned that not only were there problems with the study and the documentation of problems experienced by patients, but the companies were having major problems with quality control issues and were violating good manufacturing practices. These problems had gone on for years.

These individuals alleged that there were problems with the implant design and gel suppliers; there were defects with the implants, valves, and outer shell; and

there were inconsistencies in the gel used to fill implants. It appeared many of these problems had been concealed from the FDA. I reported this information to the FDA, several people at the FDA, but there was no apparent action.

Disturbed by the lack of responsiveness at the FDA, in the summer of 1998 I put all of the information together, information about the clinical trials and the manufacturing problems alleged by industry employees, and gave it to Congressman Green, the FDA, the House Energy and Commerce Committee, and eventually to Congressman Blunt.

The FDA's copy was given to James Austin Templer, a FDA compliance officer who oversaw Mentor Corporation, the manufacturer I had gathered the most data about. Mr. Templer referred the information to the FDA's Office of Criminal Investigations, and in 1998 a criminal investigation was opened.

Throughout 1999, I continued to receive alarming information, which was given to Mr. Templer and then forwarded to the FDA's criminal investigators. Unfortunately, little was done, in spite of the shocking information that was uncovered and Mr. Templer's efforts to push the investigation forward. It became obvious to both of us that there were significant problems with the medical devices and the integrity of the manufacturing process. Furthermore, it appeared internal problems at the FDA were undermining consumer protection.

The situation became critical in 2000. The FDA had announced that saline breast implants would be considered for market approval in the spring, and Mentor Corporation would be submitting a pre-market application (PMA) for approval of their products. The criminal investigation had gone nowhere and regulatory actions had been put on hold because of the criminal investigation. In January 2000, in frustration and out of a concern for American consumers, Mr. Templer tendered his resignation from a twelve-year career at the FDA. He hoped his resignation would get the attention of the agency. In his resignation letter to the commissioner, he, among other things, urged the agency to conduct a thorough investigation of the allegations, which had been made about the manufacturer and the study, prior to the agency's approval of saline breast implants. Unfortunately, the FDA again chose to look the other way.

In May 2000, the FDA approved saline breast implants. The approval came in spite of Mr. Templer's recommendation, in spite of complications rates as high as 43% for cosmetic patients and complication rates of over 70% for reconstruction patients (in the first 3 years), and in spite of an ongoing open criminal investigation into one of the manufacturers, which remains open even today.

Sadly, consumers believe "FDA approval" of a product means that the product has been adequately studied and has been found to be safe and effective for it's intended use. I'm not sure this should be concluded with this device. Unfortunately, the average consumer who might purchase this product will not have access to the information the FDA has ignored during the approval process, resulting in an inappropriate assumption of safety and effectiveness.

It is my fear that by ignoring the regulatory problems, the criminal allegations, the high complication rates and the recommendation of the FDA's own staff, the agency has lowered the bar for what is considered a safe and effective medical device. Additionally, the ramifications of the FDA's decision could be widespread and ultimately effect other products and many American consumers.

It was this concept which disturbed Mr. Templer and me so deeply. Mr. Templer couldn't be here today, however, he asked me to advise the committee of his professional opinion regarding this topic.

Mr. Templer writes, "Based upon information I was aware of as an FDA official it does not surprise me that breast implant recipients are experiencing significant health consequences. I was aware of many quality control issues as well as situations where FDA employees illegally assisted an implant manufacturer. I reported these issues, but the FDA wanted to sweep the matter under the rug. In my opinion, the FDA has not adequately monitored or investigated the safety of breast implants, and in fact, they have looked the other way when credible allegations of criminal conduct have been made. I urge the committee to take the actions necessary to protect the public health, because the FDA has clearly failed to do so."

I agree with Mr. Templer: it will take an act of Congress to get to the bottom of the breast implant debacle. However, Congress must insist that our country's watchdogs are doing their jobs. The passing of this bill is a great first step. S. 961, the Breast Implant Research and Information Act, will ensure the FDA has full oversight and will provide accountability. The passing of this bill will ultimately benefit women's health and could also impact FDA's oversight of all medical devices.

I want to thank Senator Barbara Boxer and Senator John Edwards their leadership on this issue.

I urge you to make it a goal to pass this bill in this Congress. Breast implants have been put in women's bodies for over 30 years; it's high time we understand the long-term effects of this product and insist that they be manufactured with integrity and in accordance with good manufacturing practices.

PREPARED STATEMENT OF JILL KAGAN

Mr. Chairman and members of the subcommittee: On behalf of the National Respite Coalition, I am pleased to submit this testimony in support of the "Lifespan Respite Care Act of 2002," to be introduced by Senators Clinton, Mikulski and Snowe. Seventy-five national, State and local organizations have already endorsed this bill, which grew out of the efforts of the National Respite Coalition's Lifespan Respite Task Force, a coalition of national organizations and State respite coalitions.

The National Respite Coalition is the policy division of the ARCH National Respite Network and Resource Center. The ARCH Network is a membership organization of respite providers, State respite and crisis care coalitions, and the families and caregivers who rely on planned and crisis respite services. The ARCH National Resource Center on Respite and Crisis Care is a federally funded resource center providing: training and technical assistance; product development including a start-up manual, National Respite Guidelines, fact sheets, training manuals and evaluation reports; a National Respite Locator Service; networking opportunities; and evaluation and research.

Over the last several years, the National Respite Coalition, following the leads of its State respite coalitions, helped spearhead a national movement to address the respite and caregiving needs of all families across generations, across disability groups, and regardless of family situation or income level. Partnering with over 25 other diverse national and State organizations in a working group called the Lifespan Respite Task Force, the NRC helped highlight the need for high quality, accessible and affordable respite services across the lifespan.

We are extremely grateful for the strong national leadership Senator Clinton, Senator Mikulski and others on the subcommittee have already shown on family caregiving issues. We strongly support the implementation of the National Family Caregiver Support Program, which is helping expand and support respite and support services primarily for caregivers of the elderly. It is an important first step and we commend you for all your efforts in this area.

WHAT IS RESPITE?

Respite care provides temporary relief for caregivers from the ongoing responsibility of caring for an individual of any age with special needs, or who may be at risk of abuse or neglect.

Respite is first and foremost a preventive strategy that strengthens families, protects the health and well-being of the family, and allows them to continue providing loving care at home. Respite is also an important component of a continuum of comprehensive family support and long-term care services that are available to caregivers not only on a planned basis, but also in the event of a crisis situation, such as sudden job loss or homelessness.

WHO NEEDS RESPITE?

The sheer numbers of women in this country, many of whom place their own emotional and physical well-being in jeopardy by providing continuous care with no break and limited support, are enough to raise and justify concern. Current estimates suggest that there are between 24 million and 28 million family caregivers in America. Nearly 45 percent are caregivers of nonelderly adults and children. The remaining are caring for the elderly. By 2020, the number of adults requiring assistance with daily living will increase to almost 40 million, requiring a tremendous spurt in the numbers of family caregivers.

This is especially relevant to women's health, since 75 percent of the caregivers nationwide are women.

Moreover, new family arrangements, such as growing numbers of grandparents caring for grandchildren, also suggest a need for new and effective support services. Currently, there are more than 2.5 million grandparent-headed households raising 3.9 million children in the U.S. The number of these families without either parent present increased 53 percent between 1990 and 1998 and now over 1.3 million children are being raised solely by their grandparents. Despite these statistics, most States and counties do not fund respite for these caregivers.

Caregivers, who are raising young children while caring for an aging parent or relative, bring their own set of stressors and add to the growing need. It is esti-

mated that between 20 and 40 percent of caregivers have children under the age of 18 to care for in addition to a parent or other relative with a disability.

In addition, families of children with disabilities or chronic illness have unique and ongoing needs that present special demands and can increase family stress. Over six million children are eligible for or receive special education and related services under the Individuals with Disabilities Education Act (IDEA). Many have estimated the number of children with serious disabilities and chronic illness to be even higher.

UNMET NEED AND THE DIRE CONSEQUENCES

Survey after survey of family caregivers has shown respite to be the most often requested family support service, and yet it remains in critically short supply.

Twenty of 35 State-sponsored respite programs surveyed in 1991 reported that they were unable to meet the demand for respite services. In the last ten years, we expect that not too much has changed. The thirty State coalitions and other National Respite Network members confirm that long waiting lists or turning away of clients because of lack of resources is still the norm.

According to the ARCH National Resource Center on Respite and Crisis Care, during an average week, nearly 1,500 families representing 3,425 children are turned away from respite and crisis care programs because resources to meet the need are absent. In the absence of any hard data, but countless compelling family stories, we know that respite for adults with disabilities and chronic illness is also in critically short supply.

The lack of support is taking its toll on caregivers. While a large proportion of caregivers, most of whom are women, report finding an inner strength they didn't know they had, a National Family Caregivers Association survey found that significant numbers report serious physical or mental health problems, including headaches, stomach disorders, back pain, sleepless nights and depression. Mortality risks are even higher for caregivers than for noncaregivers. A 1999 study reported in the Journal of the American Medical Association found that participants who were providing care for an elderly individual with a disability and experience caregiver strain had mortality risks that were 63 percent higher than noncaregivng controls.

Grandparent caregivers report face enormous financial stress, as well as the poor health status. In 1997, grandparent caregivers were 60 percent more likely to live in poverty than grandparents not raising grandchildren. In addition, one-third of grandparents in all grandparent maintained families self-report their general State of health as fair or poor.

In fact, we cannot afford to lose any family caregivers to stress or illness. According to the National Long-Term Care Survey, if the work of family caregivers had to be replaced by paid home care staff, the cost to our nation would be $45 to $75 billion per year. Other studies have suggested that caregivers now provide nearly $200 billion per year in unpaid care, saving the government billions of dollars in paid institutional long-term care costs.

Those who are being cared for are at high enough risk already without having their caregivers face uncertain illness or even death. And for many, the families suffer emotionally as well as economically. Families of children with disabilities face a significantly higher divorce rate than families of children without disabilities. Lack of respite care has even been found to interfere with parents of children with disabilities accepting job opportunities.

Even tragedy can result. The number of children and the elderly who are annually reported as abused or neglected, whose families could benefit from respite services to prevent the abuse from happening in the first place, is unacceptable. Each year, CPS agencies investigate an estimated two million reports alleging the maltreatment of almost three million children. In addition, it is estimated that two to four million women are victims of domestic violence and between 3.3 and 10 million children are exposed to domestic violence, each year. Without adequate family support, children with disabilities face an even higher risk of abuse and neglect (nearly four times higher).

The abuse rate of the elderly is also unacceptably high. Experts estimate that as many as 32 out of 1,000 elderly people are victims of elder abuse. A 1996 national incidence study found that 450,000 persons ages 60 and over in domestic settings experienced abuse or neglect in a one year period. It is estimated that over five times as many new incidents of abuse and neglect were unreported than those that were reported to and substantiated by Adult Protective Services agencies that year. In 90 percent of cases, the perpetrator is a family member.

RESPITE WORKS AND SAVES MONEY

While much more rigorous evaluation needs to be done, respite has been shown to improve family functioning, improve satisfaction with life, enhance the capacity to cope with stress, and improve attitudes toward the family member with a disability.

Most compelling are recent preliminary data from Phase One of the ARCH National Resource Center Outcome Evaluation project. Twenty-nine respite and crisis care programs serving families across the lifespan in the Midwest, South, East Coast, West Coast, Southwest, Alaska and Hawaii volunteered to participate. Seventeen programs remained engaged in the project and participated in the field-testing of the instruments. Based on their knowledge of the families' activities and past history, project managers reported that in some instances caregivers were likely under reporting on issues such as maltreatment, out of home placement and marital status. Even with some qualifications, the preliminary data are very encouraging.

Although parents were reluctant to admit that their child would have been at risk for maltreatment had crisis care not been available, caregivers reported that the crisis care they received helped protect their child from danger. Fifteen percent of the caregivers of children using crisis respite reported that it was "somewhat likely" to "highly likely" that their child might have been mistreated or neglected if crisis care had not been available, and an additional 15 percent responded "not sure." Yet, 81 percent reported that the crisis care they received helped protect their child from danger. In terms of marital stability, nearly half (47 percent) of the caregivers surveyed in respite programs serving all age groups said that they would be somewhat, quite or highly likely to experience separation or divorce without respite services.

Respite helps families avoid more costly out-of-home placements as well. Hospitalizations, institutionalization, nursing home and foster care placements have been shown to actually decline when respite or crisis care is the intervention. The Nebraska lifespan respite program conducted a statewide survey of a broad array of caregivers who had been receiving respite services, and found that one out of four families caring for a child under 21 and one out of two families caring for a family member over 21 reported that they were less likely to place their family member in out-of-home care once respite services were available.

Most importantly, the health and well-being of women and others who provide the care has been shown to improve. Sixty-four percent of caregivers of the elderly receiving 4 hours of respite per week after one year reported improved physical health, 78 percent improved their emotional health, and 50 percent cited improvement in the care recipient as well. Forty percent said they were less likely to institutionalize the care recipient because of respite. Caregivers of relatives with dementia who use adult day care experience lower levels of caregiving related stress and better psychological well-being than a control group not using this service. These differences are found in both short-term (3 months) and long-term (12 months) users. In addition, the Nebraska Lifespan Respite program found that 79–80 percent of the respondents reported decreased stress and 58–65 percent reported decreased isolation as a result of respite services received through the program.

STATE FAMILY CAREGIVER SUPPORT PROGRAMS

Over the last decade, States have begun to respond to this growing need and have implemented caregiver support programs in various forms.

In a Family Caregiver Alliance (FCA) survey of 33 caregiver support programs in 15 States, it was found that eligibility criteria for programs vary widely by diagnostic/functional level, age and income. Over two thirds of these programs provide five or more caregiver services, most typically respite care. For respite assistance in particular, service definition, eligibility, mode of delivery and funding vary widely across programs and within States. Key informants report that while respite care is among the most beneficial aspects of their programs, recruiting respite workers/raising worker wages is also among the biggest challenges these State programs face.

Oregon's Lifespan Respite Care Program (see below) was identified as one of the five best practice models among the 33 programs surveyed by FCA and at the time of the survey was the only statewide program with no eligibility criteria based on disability, income, or age. Wisconsin, Nebraska and Oklahoma now all have statewide lifespan respite programs (see below). The private sector, including Easter Seals, United Cerebral Palsy, and the Alzheimer's Association are also involved in providing and supporting respite services. An intergenerational program, Family Friends, partners active senior volunteers with families of children with disabilities to provide respite, friendship and nurturing.

FRAGMENTATION AND UNMET NEED

Despite the model efforts discussed so far, and the success respite brings in terms of family stability and cost-savings, the need for State and national respite care infrastructure is compelling. Most of the problem can be attributed to insufficient resources directed specifically at start-up, development, implementation and maintenance of quality respite care choices.

The current supply of individuals available to provide respite care is woefully inadequate in many communities, especially respite care for individuals with certain disabilities such as mental illness or severe medical conditions, especially those over age 18, or in some rural and urban centers where these resources may be scarce.

However, an equally difficult problem is the identification and coordination of existing resources that would aid caregivers and help State agencies improve access to respite programs.

Implementation of the National Family Caregiver Support Program is helping develop statewide infrastructures and single points of entry through Area Agencies on Aging to help primarily caregivers of the elderly more easily find the respite and support they need. Existing statewide respite and caregiver support programs are also a small step in the right direction, providing access to some respite services statewide for some part of the needy population.

While these efforts provide a critically important foundation on which to build, they currently do not do enough to reduce the fragmentation, the inaccessibility, and the confusion that exists around multiple eligibility criteria, numerous funding streams, and qualified provider shortages.

Numerous funding sources with different eligibility criteria are partly to blame.

A myriad of other Federal programs, including Medicaid, Medicaid Waiver programs, Title XX Social Services Block Grant, the Community-Based Family Resource and Support Program, the Child Care and Development Block Grant, and the Developmental Disabilities Program, among others, have been identified which have the potential to fund or support respite care for caregivers, but only for caregivers of individuals with specific disabilities, specific ages, or for one narrow purpose.

These limitations are confusing not only to families, but to the States that rely on them. In addition, while many of these programs have the potential to fund respite and crisis care, they are not mandated to do so. Competing demands for these funds or lack of information on the part of consumers as well as State agency heads often results in no or limited Federal funds from these various programs being used to support respite care.

Currently, there is no single, coordinated, family/caregiver friendly Federal program to support the development or implementation of respite care infrastructures that would serve all families regardless of the age of the caregivers or the ages or disabilities of the care recipients. Families are now forced to search for services, funding, and support, where they may or may not exist, often in a complicated bureaucratic maze.

LIFESPAN RESPITE

As of April 2002, three States had passed Lifespan Respite Acts (Oregon, Nebraska, Wisconsin), which establish State and local infrastructures for developing, providing, coordinating and improving access for respite to residents of the State. Oklahoma has implemented a statewide Lifespan Respite Program without legislation. Maryland has enacted legislation that establishes a State Coordinating Council for Family Caregiver Support. Part of Maryland's charge is to review successful lifespan respite care programs in other States, develop a model family caregiver support program that incorporates best practices from existing programs in the State and in other States; and coordinate activities of existing and proposed family caregiver support services among the State and local public agencies. Several other State coalitions or governments (Alabama, Connecticut, Florida, and Montana, among others) are actively considering or piloting similar lifespan respite programs or legislation.

Each program has been adapted to meet their individual State needs, but the defining characteristic of each is the statewide, coordinated approach to ensure respite services for all who need it. Many of the lifespan respite programs have established community-based networks that rely on the development of local partnerships to build and ensure respite capacity. These local partnerships include family caregivers, providers, State and federally funded programs, area agencies on aging, nonprofit organizations, health services, schools, local business, faith communities and volunteers.

These networks are the central point of contact for families and caregivers seeking respite and related support regardless of age, income, race, ethnicity, special need

or situation. Providing a single point of contact for families to access respite is crucial to assisting families in helping themselves.

Services typically offered by Lifespan Respite Programs are providing public awareness information to the community and building diverse respite partnerships, recruitment of paid and volunteer respite providers, connecting families with respite payment resources, coordinating respite related training for providers and caregivers, identifying gaps in services and creating respite resources by building on existing services, and connecting families with respite providers.

Oregon was the first State to implement a Lifespan Respite Program in 1997. The Director of the Oregon Department of Human Services (DHS) is charged by State law to develop and encourage statewide coordination of respite care services. The Department works with community-based nonprofits, businesses, public agencies and citizen groups to identify gaps in services, generate new resources and develop community programs to meet those needs. Oregon's Lifespan Respite Program is housed in the DHS Community Partnership Team and is responsible for implementing the Oregon Lifespan Respite Care Act, administrative rules, contracts, funding and program evaluation. The Program offers technical assistance with program specific issues, works directly with Lifespan networks and promotes the State respite agenda. Currently there are 29 Lifespan Respite Care Networks representing 34 Oregon counties. All of Oregon's counties are expected to be served by 2003.

Nebraska builds on the Oregon model and is currently administered by the State's Department of Health and Human Services, which established the Nebraska Lifespan Respite Services Program. With the goal of helping create a permanent structure for a statewide system for respite, NLSRP designated and funded six community lifespan programs this past year. The organizations which received the contracts with Health and Human Services will be expected to accomplish the following five outcomes within the initial two-year contact period: (1) A knowledge of all existing respite resources within the designated HHS service area and the need for additional resources by lifespan populations; (2) An increased public awareness of lifespan respite among families, providers, local agencies, Medicaid staff and the private sector within the designated HHS Service Area; (3) An increase in the access to lifespan respite services; (4) Knowledge of and collaboration with existing agencies on best practices for a comprehensive training package for providers and family members; and (5) Documentation of an increase in the awareness of respite, an increase in Medicaid respite providers, an increase in the representation of all cultural groups, better access to respite services and other baseline data established by HHS to be used for program evaluation.

In Wisconsin, the legislation authorizing the Wisconsin Lifespan Program requires that coordinated, noncategorical respite services be available locally to provide reliable respite services when needed by families and caregivers regardless of age, disability or geographic location in Wisconsin. In collaboration with the Department of Health and Family Services, the Respite Care Association of Wisconsin (RCAW), the State administering body of the Wisconsin Lifespan Respite Program provides administrative oversight to the lifespan grantees, offers technical assistance around program and workforce specific issues, and promotes the State respite agenda. In 2000, RCAW awarded grants to establish five regional lifespan programs, one in each of the five Department of Health and Family Services regions across the State. By 2005, it is expected that 25 lifespan projects will be created in the State.

The Oklahoma Respite Resource Network (ORRN) is a statewide partnership of public and private agencies whose goal is to support families and caregivers by increasing the availability of respite care. State agencies, including developmental disabilities, mental health, aging, maternal and child health and others, have come together voluntarily with private agencies to pool resources for respite and dispense them though a voucher program managed by a single State program. Families applying to the State for a respite voucher (families are entitled to $400 in vouchers for 3 months) are considered the employer of the respite care provider and are encouraged to consider as potential respite providers family, friends or co-workers, civic organizations, local churches, child care centers, or other appropriate public or private agencies. The Oklahoma Respite Resource Network also relies on an already existing statewide resource and referral system (OASIS) to link families to the program.

TIME HAS COME FOR A NATIONAL LIFESPAN RESPITE POLICY

Building on the fervent activity at the State level, and the converging demographic and social trends that face all families and caregivers across the nation, the National Respite Coalition has found unprecedented support among a diverse group of national organizations for pursuing a national lifespan respite policy.

The NRC held a National Summit on Lifespan Respite in May 2000. Over thirty national organizations attended and a core group has been meeting as the Lifespan Respite Task Force regularly since then. Our first major activity was the development of a common respite definition, a vision statement and a set of principles of quality respite care. Twenty-seven national organizations and 17 statewide organizations endorsed the vision statement and principles.

The Task Force's efforts were bolstered by the National Conference of State Legislatures response to assist States in planning around the Olmstead decision, a Supreme Court decision which requires every effort by the Federal Government, States and local agencies to serve individuals with disabilities in the community, rather than in institutional settings. NCSL published an issue brief on implementing long-term care in community-based settings which highlighted lifespan respite as one of three best practices models for State action. The Nebraska program was highlighted as an example.

We are also heartened by the Administration's Department of Health and Human Service's focus on respite care for supporting family caregivers during implementation of the Olmstead decision in its recently released report "Delivering on the Promise." Recommendations included two new demonstrations for respite for the adults with disabilities and for children with severe disabilities to be administered through the Center on Medicaid and Medicare. While we applaud the Department's recognition that respite is needed by all age groups, and their efforts to increase the availability of respite care, it is another piecemeal approach that does not go as far as the Lifespan Respite Care Act of 2002 to ensure that duplication and fragmentation of services are eliminated, and that barriers to quality respite care across the lifespan will be reduced for caregivers struggling to keep their loved ones at home.

LIFESPAN RESPITE CARE ACT OF 2002

We know how families are changing and how rapidly a large proportion of the population is aging. The demographics make that clear. Fortunately we know what to do to support families. We commend the cosponsors of the "Lifespan Respite Care Act of 2002" for following the States' leads to make sure that every State has the resources and encouragement to institute their own lifespan respite program. This bill would authorize funds for:

- development of lifespan respite programs at the State and local levels; evaluation of such programs; planned or emergency respite care services;
- training and recruitment of respite care workers and volunteers; and
- caregiver training to help make informed decisions about respite care services.

Lifespan respite programs are defined in the bill "as coordinated systems of accessible, community-based respite care services for all caregivers of individuals regardless of the individual's age, race, ethnicity or special need."

Caregivers who are family members (including grandparents caring for grandchildren), foster parents, or other adults providing ongoing unpaid care for an individual with a special need. Special need is defined broadly as: Alzheimer's disease and related disorders; developmental disabilities; mental retardation; physical disabilities; chronic illness; behavioral, mental and emotional conditions; situations in which there exists a high risk of abuse or neglect or of being placed in the foster care system; in which a child's parent is unavailable due to parent's death, incapacitation, or incarceration of a parent; or any other conditions established by regulation.

Funds would be provided on a competitive grant basis to State agencies, other public or private nonprofit entities capable of operating on a statewide basis, a political subdivision of a State that has a population greater than three million, or any already recognized State respite coordinating body. Priority would be given to applicants that show the greatest likelihood of implementing or enhancing lifespan respite care statewide.

Coordination is also required at the Federal level between the administering agency, the Maternal and Child Health Bureau of the Health Resources and Services Administration and the following Federal agencies: National Family Caregiver Support Program of the Administration on Aging, the Administration for Children, Youth and Families, the Administration on Developmental Disabilities, and the Substance Abuse and Mental Health Services Administration.

Funding for the bill is authorized at $90.5 million in fiscal year 2003 and rises to $200 million in fiscal year 2007. The bill would also establish authority for a critically needed National Resource Center on Lifespan Respite Care that would assist States and local programs in developing and enhancing new respite services; maintain a national database; provide training and technical assistance, and information to the public on lifespan respite care.

This legislation is timely and will help create a family caregiving policy in our country, not just a band-aid solution. Families are under greater stress than ever before and the numbers of women who will assume caregiving roles without adequate support in the coming decades are rising at an alarming rate. Respite works, respite saves money, and it's what families and caregivers say they want and need.

Thank you for the opportunity to provide written testimony to the committee in these very important deliberations. The National Respite Coalition stands ready to provide assistance in rapid enactment of this critically important legislation.

PREPARED STATEMENT OF SUSAN SCANLAN

The Women's Research and Education Institute (WREI) appreciates the opportunity to submit this statement to the record of the Senate Health, Education, Labor and Pensions Public Health Subcommittee's April 25, 2002 hearing on women's health. Established in 1977, WREI is an independent, nonprofit organization which gathers, synthesizes, and analyzes policy-relevant information on issues that concern or affect women, and serves as a resource for Federal and State policymakers, scholars, advocates for women, the media, and the public.

WREI commends the subcommittee for holding this hearing and drafting this important piece of women's health legislation. For years, improving women's health has been one of WREI's high priority areas. Described in greater detail below, WREI's most recent project, Improving the Health of Midlife Women, charts a Federal health policy agenda for the 21st century, and serves as a blueprint highlighting areas where Congress can make a significant difference in promoting health and preventing disease. While WREI's recommendations are focused on mid-life women, they often apply equally well to women's health issues across the lifespan.

WREI was heartened to learn that several of our highest priorities, such as establishing permanent offices of women's health and expanding the WISEWOMAN program, are already included in the bill. These components of the legislation would help to coordinate women's health programming across Federal agencies, and provide low-income and uninsured women with critical heart disease screening, intervention, and case management services. WREI is also pleased that other high-priority recommendations, such as providing women with direct access to OB/GYNs, are included in pending legislation.

WREI'S HIGH PRIORITY POLICY RECOMMENDATIONS

In addition to establishing permanent offices of women's health and expanding the WISEWOMAN program, WREI believes that a number of our high priority policy recommendations would be appropriate to include in the comprehensive bill. Specifically, we would like to highlight our recommendations to expand the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), and for Congress to direct the Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC) to develop community health centers as sites for health promotion and disease prevention for all women. Both of these recommendations would improve crucial health promotion, screening, and treatment services for low-income, rural, and underserved women.

As WREI's report points out, a number of gaps exist in midlife women's access to health promotion and disease prevention services. Far too many women, especially women with low incomes and women of color, are not receiving the screening services that could increase the likelihood of early detection and successful treatment of diseases. While some screening rates have improved in recent years, there is much more that should be done to bring the rates up.

In the NBCCEDP, women between the ages of 40 and 64 are eligible for a Pap test, and women between 50 and 64 years old are eligible for a mammogram. Due to limited funding, however, the NBCCEDP reaches only 15% of the eligible population. In order to provide more women with access to NBCCEDP education and screening services, WREI urges Congress to increase appropriations and expand this important program. Even a small expansion would be a step in the right direction.

In addition to expanding the NBCCEDP and the WISEWOMAN programs, Congress could further increase access to crucial preventive and screening services by eliminating copayments for such services. Public education efforts could also encourage health care providers to adopt a comprehensive approach to screening women for a number of diseases, such as heart disease and osteoporosis.

WREI also recommends that Congress expand community health center programs to provide additional services to unserved and underserved women, especially midlife women. Programs are needed to encourage self-management of chronic disease, counseling on health behaviors and preventive health options, and screening for chronic diseases and conditions. Recognizing CDC's capacity in chronic disease pro-

grams in the States and HRSA's capacity to provide services to underserved women, these two agencies should be encouraged to work together to develop community health centers as sites for health promotion and disease prevention.

WREI'S REPORT ON IMPROVING THE HEALTH OF MIDLIFE WOMEN

WREI undertook its latest project on midlife women's health because of our strong belief that a comprehensive health policy agenda aimed at midlife women is urgently needed. Until recently, most of the policy attention has focused on younger women of reproductive age and older women who are eligible for Medicare. However, the years between 45 and 64 are a time when many women are at serious risk for the onset of chronic conditions such as heart disease, cancer, diabetes, arthritis, and osteoporosis. The Federal Government has an important role to play in educating midlife women, the public, and clinicians about women's health risks and in improving women's access to crucial preventive services.

In January 2001, WREI brought together a broad cross-section of policymakers, Federal agency personnel, and representatives of advocacy groups and foundations for a two-day summit to identify the major gaps in midlife women's health and to chart a Federal health policy agenda. These experts identified 10 gaps in the health of midlife women and 46 policy options to close those gaps.

Following the summit, WREI selected 15 high-impact actions Congress and the Administration should take to make a significant difference in promoting health and preventing disease in midlife women (attached). The full report, Improving the Health of Midlife Women: Policy Options for the 21st Century, describes the gaps and policy options in detail. WREI would like to request that the attached summary of the 15 high-impact recommendations be included in the hearing record.

Similar to the bill the committee is developing, WREI's recommendations can be categorized into prevention, research, and treatment initiatives. Of the 46 recommendations, 44 fall into prevention, 9 into research, and 25 into the treatment category. Not surprisingly, the overwhelming majority of the recommendations focus on prevention, and many would require an additional investment of resources. While Congress might be hesitant to appropriate these funds, WREI believes that a significant investment in disease prevention and health promotion now would result later in improved quality of life, less mortality, and health care cost savings due to reduced treatment expenses. It is better to prevent disease in the first place than to treat it after it has already developed.

As WREI's report highlighted, many women between the ages of 45 and 64 lack access to preventive health care. Millions have no insurance coverage at all; millions more have private plans that require hefty deductibles and copayments. The development of strategies for extending health insurance coverage to uninsured women is urgently needed.

Finally, the report emphasizes the need for more research on health promotion and disease prevention for women. A number of studies are currently underway at the National Institutes of Health and other Federal agencies. Still, we know far too little about what works in health promotion and disease prevention for women in midlife. We need additional research on what motivates women to change unhealthy behaviors, on barriers to change, and on how best to help women practice healthy behaviors. Research is also needed on the sociocultural and financial barriers to preventive health care, as well as on the factors that discourage physicians from providing comprehensive, preventive health care and appropriate counseling to women about health promotion and disease prevention.

Much progress has occurred in recent years in improving the health of women, and this committee can take much of the credit for these improvements. In closing, in addition to the specific recommendations we have outlined, WREI urges the committee to examine our report and recommendations, and determine if any of the other provisions could be incorporated into your bill. WREI applauds the committee for all its hard work, and looks forward to continuing to work with you and your colleagues to improve women's health.

PREPARED STATEMENT OF PAMELA NOONAN-SARACENI

Mr. Chairman, my name is Pam Noonan-Saraceni. As a breast cancer survivor who continues to endure the painful physical side-effects of silicone breast implants, I am pleased to have the opportunity to take part in this hearing.

Many believe the scientific and safety debate on breast implants is over and are wondering why breast implants are part of today's hearing. You believe this issue has reached its saturation point. But, breast implants remain a classic example of "what we don't know can hurt us."

Consider the number of women who have breast implants. The Institute of Medicine estimates that by 1997, 1.5 to 1.8 million American women had breast implants with nearly one third of these women being breast cancer survivors. In 1999 alone, nearly 83,000 women received implants following a mastectomy. In 2000, over 200,000 women received breast implants for cosmetic reasons.

Yet, in 1999, the Institute of Medicine concluded:

• First, reoperations and local complications are frequent enough to be a cause for concern and to justify the conclusion that they are the primary safety issue with silicone breast implants;

• Second, risks accumulate over the lifetime of the implant, but quantitative data on this point are lacking for modern implants and deficient historically;

• Third, information concerning the nature and relatively high frequency of local complications and reoperations is an essential element of adequate informed consent for women undergoing breast implantation.

And in 1997, the Mayo Clinic found that one in four women required additional surgeries within five years of implantation because of problems related to the implants. The rate was higher for mastectomy patients: one in three women.

Despite over thirty years of use, the Food and Drug Administration has never approved silicone implants and just recently approved saline implants for the first time. Little is known about the long term effects of silicone and even less is known about saline. Yet their popularity is growing with a new generation of young women who, in spite of the past controversy, are being led to believe that improvements have been made to these implants, and therefore, they are now safe.

I believe breast implants should be an option for women. But, a safe option. Therefore, the role of the Government cannot be overlooked. There are a number of measures that the Federal Government could implement to better protect women and preserve their health and their quality of life. These measures are encompassed in the legislation introduced by Representatives Roy Blunt and Gene Green. H.R. 1961, "The Breast Implant Research and Information Act," calls upon the FDA to strengthen informed consent documents given to patients in clinical trials for breast implants; directs the National Institute of Health to conduct independent research desperately needed on breast implant recipients; and ensures better FDA oversight of device manufacturers.

In order to better understand the need for this legislation, I would like to tell you a little bit about my personal experience. I was diagnosed with breast cancer and had a radical mastectomy in 1978. I was just 25 years old at the time. I waited 5 years before I decided to have reconstructive surgery. I was an active person. I played tennis, taught aerobics, and jogged. I had grown tired of the inconvenience of the prosthesis shifting and falling out when I perspired. I thought I had done my homework on breast implants prior to choosing the plastic surgeon to do my reconstruction. However, I was never advised of any of the health risks associated with the implants. In fact I was told repeatedly that they would "last a lifetime" and that "complications" were rare. Within 3 months of the initial reconstruction, I was back in the operating room. My body had formed a capsule around the implant and the implant had shifted up toward the collarbone. My symptoms of physical illness began slowly. In the summer of 1990 I began to experience joint pain and chronic fatigue. This was six years after my being implanted. I have been to various doctors and specialists and have a list of various diagnoses. Before I had the implant removed in June of 1994 (10 years after the initial reconstruction), I had to wear a partial prosthesis over the implant. Capsular contracture had again become a problem and I was misshapen and lopsided. The explantation was the 5th surgery at my breast site.

To date, my out of pocket medical expenses total almost $35,000. My husband and I are self-insured. The insurance policy that we took out in 1991 had an exclusion. I was not covered for any illness or disabilities related to the reconstructive surgery. Apparently, the insurance companies understood the health risks breast implants pose for women and were not willing to bear the financial costs. I believe there are several areas that need improvement in order to protect women considering breast implants. The Breast Implant Research and Information Act, introduced by Senator Boxer and Congressmen Gene Green and Roy Blunt, is a tremendous step forward to safeguarding American women.

FIRST: INFORMED CONSENT MUST BE STRENGTHENED

Insufficient and inaccurate information has posed many problems for women in breast implant trials. Even the Institute of Medicine recognized that women are not being adequately warned of rupture, painful local complications and multiple surgeries.

The informed consent agreement drawn up by the breast implant manufacturers is the only required information women receive about the implants and the study prior to surgery. This document contains inaccurate data on rupture and contracture rates, the efficacy of the implants, the risks and complications, and the need for future reoperations. It understates the FDA's concern about the safety of silicone breast implants, which first led to the 1992 moratorium, and makes many misleading statements about the rate of complications following implantation.

Furthermore, the informed consent agreement does not mention the effects of breast implants on future mammography. This is probably not a concern most cosmetic patients even consider. Yet, over 30 percent of the breast tissue can be obscured by the implant, which can delay the detection of cancer.

Until independent research is able to answer the long-term safety questions surrounding breast implants, women, at the very least, need to be informed about what we DO know:

- chronic pain, breast hardening, infections and breast deformity;
- the high rate of reoperations;
- the high rate of ruptures;
- problems associated with insurance coverage;
- the fact that implants do not last a lifetime and will have to be replaced every 8–10 years;
- inaccurate mammography.

SECOND: THE NEED FOR LONG-TERM STUDIES

The Breast Implant Research and Information Act directs the National Institutes of Health to conduct the independent research that is so desperately needed in this area. The lack of convincing data submitted by the manufacturers or the plastic surgeons on the incidence of device failure, implant rupture or gel bleed was of concern to the FDA in the early 1980s—so much of a concern that an FDA panel headed by Dr. Norm Anderson recommended that silicone breast implants remain a Class III device, meaning their safety and efficacy was not proven.

Once product liability cases involving silicone breast implants became more and more common, the manufacturers began to pour money into new scientific research on breast implant safety. Dr. Anderson implored the manufacturers to put their money into an independent fund so that impartial scientists could decide which issues should be examined. His wish was not granted, and the ensuing research in large part ignored long term outcomes, incidence of device failure, the consequences of implant rupture, and the causes for tissue pain.

The latency period for breast implant complications and ruptures has been widely recognized in scientific circles. I had my implants for six years before my symptoms began to appear. But, the FDA only required manufacturers to follow women in saline implant trials for three years, and the agency recently announced that manufacturers of silicone breast implants will only be required to follow patients for 2 years in order to glean data for market approval. These studies will not provide meaningful data on the long-term safety and efficacy of the implant, and will do little to protect American women in the long run.

In its review of breast implant studies, the Institute of Medicine also concluded, "risks accumulate over the lifetime of the implant, but quantitative data on this point are lacking for modern implants and are deficient historically."

In May of 1999, University of Florida researchers published their analysis of more than 35 studies, which examined more than 8,000 implants. According to this analysis, silicone breast implant rupture rates were found to be 30 percent at 5 years, 50 percent at 10 years and 70 percent at 17 years. According to the researchers, past studies that have been cited in support of silicone breast implant safety have "paid almost no attention to the health consequences of local complications of pain, capsular contracture, disfigurement, chronic inflammation, rupture, silicone migration, and frequent surgical revisions." They conclude that the longer women have these devices in their bodies, the greater the risk of failure and numerous complications.

This study and the IOM review reinforce the need to study women for a long period to accurately assess the health effects of breast implants.

Furthermore, almost no research has been done to track mastectomy patients who suffer from local complications at a higher rate than other breast implant recipients.

I hope one day there is a cure for breast cancer. But until that day, the National Institutes of Health should be obligated to conduct the independent research so badly needed on breast implants. No woman should be put in a position of surviving breast cancer only to experience chronic pain, infections, or deformities from breast implants.

CONCLUSION

When I opted for reconstructive surgery using breast implants, I thought I had made an informed decision. I asked questions of my doctors; I read as much information as was available in 1983. I thought I was making a safe choice for myself. Almost immediately, I was back in the operating room. It took six years before I began to experience unusual and chronic pain in my joints. A series of doctors diagnosed me with several different illnesses, and I underwent two additional surgeries. Finally, ten years after my initial implantation, I had the implants removed and my symptoms began to improve.

Despite the breast implant manufacturers advertisements, breast reconstruction is not an essential part of the recovery process; being cancer free and feeling physically well enough to return to a normal life is. Had I known the additional physical, emotional and financial hurdles I would have to overcome due to breast implants, I would have made a different decision. I would have never chosen implants.

My personal story and what I've learned from the experiences of women like me across the country and around the world is my only breast implant expertise. I feel a tremendous responsibility to increase awareness about the unanswered safety questions that still surround breast implants. My hope is that other women, when faced with the same choices, can make their decisions based upon better informed consent and independent research. Please support the passage of S.1961, the Breast Implant Research and Information Act.

PREPARED STATEMENT OF ESTA SOLER

Chairman Kennedy, Ranking Member Frist and members of the subcommittee, my name is Esta Soler and I am the President of the Family Violence Prevention Fund. The Fund is a national nonprofit advocacy organization dedicated to ending domestic violence through prevention, public education and advocacy for victims and their children. I would like to thank you for the opportunity to address this committee with regard to the urgent need for the health care system to do more to prevent family violence and assist families facing abuse.

PREVALENCE AND HEALTH CONSEQUENCES OF ABUSE

Domestic violence is a health care problem of epidemic proportions. Experts estimate that 25 to 31 percent of women in the United States have been abused by an intimate partner at some point in their lives. In addition to the immediate trauma and injury caused by abuse, domestic violence can cause serious physical and mental health problems that last a lifetime. It contributes to chronic conditions including neck, back and pelvic pain, ulcers, migraines and arthritis, and victims of domestic violence suffer from higher rates of mental health problems including depression, anxiety, post-traumatic stress disorder and suicide attempts. Patients experiencing abuse also are more likely to have adverse health risk behaviors such as smoking, substance/alcohol abuse and poor diet.

Battered women can have great difficulty accessing health care. The control exercised by batterers—and the isolation that results—often mean that battered women are less likely to engage in preventative health behaviors and to make or keep well woman/well child appointments, have mammograms and access early pre-natal care. Managing chronic illnesses such as asthma, diabetes and hypertension may also be problematic for abused women because batterers frequently deny them access to money and transportation and prevent them from keeping medical appointments or getting medicine.

In particular, pregnant women are at a risk. Some 240,000 pregnant women each year are abused by their partners. A recent study showed that homicide, including intimate partner homicide, is the leading cause of death for pregnant women. Abused pregnant women are also significantly more likely to experience complications of pregnancy including low weight gain, anemia, infections and first and second trimester bleeding. Victims of domestic violence are more likely to have gynecological problems during pregnancy than women who are not abused. In addition, battered women have higher rates of sexually transmitted infections including HIV, as well as depression, suicide attempts, and tobacco, alcohol and illicit drug use.

Children can also suffer greatly when they are exposed to domestic violence. Three to ten million children witness domestic violence each year in the United States. The greatest immediate risk for children who live in violent homes is that they will be physically abused. In 30 to 60 percent of families experiencing intimate partner violence, children also are abused. Children who are exposed to violence are more likely to become both perpetrators and victims of domestic violence. They often show symptoms associated with posttraumatic stress disorder and they are more

likely to have cognitive and behavioral problems including depression, anxiety and violence towards peers. They are more likely to attempt suicide, abuse drugs and alcohol, run away from home, engage in teenage prostitution and commit sexual assault. Fortunately, children can often overcome the harm caused by witnessing abuse with interventions and developmentally appropriate mental health services. However, without these interventions, the impact of childhood exposure to violence often lasts a lifetime. Adults who experienced adverse childhood experiences, including domestic violence, are more likely than other adults to smoke, abuse drugs or alcohol, and suffer from depression and obesity. They are also at significantly higher risk for health problems associated with those poor health behaviors, including cardiopulmonary disease, heart disease, diabetes and suicide attempts.

ROLE OF THE HEALTH CARE SYSTEM

The health care system often plays an important role in identifying and preventing serious public health problems, and we believe the health care system can play a unique and pivotal role in domestic violence prevention and intervention. Virtually every American woman interacts with the health care system at some point in her life—whether it is for routine care, pregnancy, childbirth, illness, injury or to seek care for her child. Women who are abused also frequently seek health care for illnesses and injuries resulting from the violence they face. In fact, a November 1998 report of the National Institute of Justice and the Centers for Disease Control and Prevention found that women make 693,933 visits to health care providers per year as a result of injuries resulting from physical assault. The majority of these visits are for treatment of injuries that were inflicted by intimate partners. This study only measured the impact of specific injuries directly related to physical assault; experts believe the numbers would be significantly higher if it had examined visits for other health problems related to domestic violence and how abuse affects the management of other illnesses.

AN URGENT NEED FOR SCREENING AND INTERVENTION

We are convinced that the models developed to prevent other chronic health problems can be effectively applied to domestic violence. Recent experience with AIDS, smoking, breast cancer and cardiovascular disease support the efficacy of screening as a tool to identify health problems and intervene effectively. Domestic violence is more prevalent than diabetes and breast and cervical cancer—conditions that health care professionals screen for on a routine basis—yet screening for domestic violence is much more rare.

By not screening for domestic violence and inquiring about abuse, health care providers often fail to recognize or address the underlying cause of battered women's health problems. Even when domestic violence results in injuries that were clearly inflicted by another person, health care providers too often treat and record the injuries without inquiring about the cause.

Providers also miss opportunities to intervene early, before a woman is injured, by not routinely screening for violence. A study published in the Journal of the American Medical Association in August 1999 found that less than ten percent of primary care physicians routinely screen for domestic violence during regular office visits. These wasted opportunities literally cost battered women their lives.

Fortunately, that practice is beginning to change. For almost two decades, a host of national health care organizations and experts have called for programs that educate health care providers about intimate partner violence and promote routine screening and intervention. The American Medical Association, American Nurses Association, American Psychological Association, American College of Obstetricians and Gynecologists, American Academy of Pediatrics and, most recently, the Institute of Medicine have all developed guidelines or recommendations for improving providers' response to family violence. In addition, the Family Violence Prevention Fund's "national screening for intimate partner violence consensus guidelines" are widely used.

Routine screening, with its focus on early identification and its capacity to reach patients whether or not symptoms are immediately apparent, is the starting point to improve medical practice for domestic violence. Routine and multiple face-to-face screenings by skilled health care providers can markedly increase the identification of domestic violence. Routine—rather than indicator-based—screening increases opportunities to identify and intervene with patients who present with symptoms not generally associated with domestic violence. Several studies demonstrate the importance of conducting inquiries in private settings and using straightforward, nonjudgmental questions, preferably asked verbally by a health care practitioner.

This kind of screening gives women a valuable opportunity to tell their providers about their experiences with abuse, and battered women report that one of the most important parts of their interactions with their physicians is being listened to about their abuse. When victims of domestic violence or those at risk for abuse are identified early, providers can help them understand their options, live more safely within the relationship or safely leave the relationship. In one study, a ten minute intervention was proven highly effective in increasing the safety of women abused during pregnancy. All these interventions can lead to reduced morbidity and mortality.

This work is being successfully tested. The Family Violence Prevention Fund is working in 15 States to improve the health care response to domestic violence. These State-based programs are demonstrating that improved collaboration and coordination between battered women's advocates, health care leaders, policy makers and public health officials can strengthen health care services to victims of domestic violence.

Due in part to these efforts, screening and intervention is becoming the standard of care. More than 20 States now have laws addressing the health care system's response to domestic violence. The Joint Commission on the Accreditation of Health Care Organizations developed standards for emergency departments about how to respond to abuse, and has now expanded those guidelines for all departments in hospitals. The coding clinic guidelines issued by the American Medical Association, the American Hospital Association and the American Health Information Management Association also require coding domestic violence in medical records.

Finally, research shows that patients support screening practices. In fact, in four different studies of survivors of abuse, 70 to 81 percent of the patients asked said that they would like their health care providers to ask them privately about intimate partner violence.

RECOMMENDED LEGISLATION

Because domestic violence is so prevalent and has such detrimental health, social and economic consequences, there is an urgent need for more serious and ongoing attention from the health care system and from our elected officials.

We are heartened, however, by the actions of this committee and efforts of many Senators here on behalf of battered women and their children. Senator Wellstone's Screening and Services Act will make a tremendous difference to abused women and their children. By funding demonstration projects to improve collaboration between the health care system and advocates for victims of abuse, this legislation will help ensure that women are treated appropriately and that a full system of care and services will be available to them. This bill will lead to more effective interventions, more coordinated systems of care, greater resources to educate health care providers and, ultimately, more women disclosing abuse and receiving help. In addition, providers who can recognize abuse in their patients will more effectively address the health implications of the violence their patients are experiencing. Without resources to promote this collaboration, efforts may be duplicative and health systems will struggle with the grave consequences of their failure to effectively help patients experiencing domestic violence for years to come.

The legislation also targets specific funds to federally qualified health centers and requires providers participating in the National Health Service Corps to be trained in the dynamics of domestic violence. Local community health centers deal with family violence every day, and many are doing an excellent job of identifying, treating and referring patients, when appropriate. However, much more work needs to be done to ensure that providers throughout the nation have the knowledge and specific training necessary to intervene appropriately.

TRAINING OF HEALTH CARE PROVIDERS

Other legislative proposals being addressed during this hearing are critical to a strengthened health care response to domestic violence. Health care providers should be trained early in their professional careers. Medical and nursing schools, as well as dental and physician assistant programs, need to teach their students in a substantive way about domestic violence. Providers often report that they don't view domestic violence as a health issue, but rather as a social problem, and one that they're not equipped to handle in our current health care environment. If we train physicians and other providers early about the health care implications of domestic violence, we will have greater success in making preventive screening routine.

Senator Boxer's bill, S. 518, The Domestic Violence Identification and Referral Act, will encourage schools that train health professionals to give their students the education necessary to properly screen for, identify and treat victims of domestic vi-

olence. Its approach of providing preference in Federal funding to programs that do provide "significant training" also will have no budget implications, since it will only address the awarding of grants that have already been funded.

RESEARCH NEEDED

In addition, we need funding to improve the research around family violence and the quality of the training for health care providers and researchers. Senators Durbin and Collins are sponsoring S. 2009, the Family Violence Prevention Act, to provide much needed funding for research. Based on a recent report from the Institute of Medicine, this legislation will support research in medical education and effective interventions to address family violence. Specifically, we applaud the bill's focus on outcomes-based research and effective interventions as they relate to women's safety and the impact of witnessing violence on children. Their bill targets areas where new research needs to be focused, including:

- Patterns of health care utilization by victims of family violence, the effects that family violence has on victims' health status, and the health care costs attributable to family violence;
- The effects of family violence on other health conditions and preventive health behaviors;
- The relationship between childhood exposure to domestic violence and child and adult health and safety;
- Effective interventions for children exposed to violence;
- Strategies to inform and mobilize public action for prevention; and
- The effects of mandatory reporting requirements on victims' safety and likelihood of receiving appropriate care and services.

We are particularly appreciative of their efforts to include domestic violence experts as members of a team that will review the types of research funded, further building the bridge between the research and advocacy communities.

MENTAL HEALTH SERVICES WANTED

Finally, we see great hope in the two bills introduced by Senator Edwards to improve mental health services for victims of domestic violence. While not all battered women experience mental health or substance abuse problems, many women and their children do need and request services to deal with the effects of the violence. The consequences of not receiving help can be severe. Twenty-nine percent of all women who attempt suicide are battered, 37 percent of battered women have symptoms of depression, 46 percent have symptoms of anxiety disorder, and 45 percent experience post-traumatic stress disorder. Children who witness domestic violence are more likely to exhibit behavioral and physical health problems including depression, anxiety and violence towards peers. As noted earlier, they are also more likely to engage in a host of harmful behaviors.

Unfortunately, many of the women who need mental health services for themselves or their families often lack the resources to access services in their communities or live in communities where services simply are not available. The Counseling in Shelters Act and the Women in Trauma Act would give women and their children access to needed mental health services in a safe and caring setting. Importantly, they would also improve coordination between and support cross-training for domestic violence advocates and mental health providers. This legislation would fill a critical void in our efforts to help battered women and their children repair their lives.

Again, Mr. Chairman and members of the committee, I would like to thank you for holding this hearing and for your efforts on behalf of the nation's battered women and their children. These pieces of legislation to improve the health care system's response to domestic violence and provide resources for victims are greatly needed. Your efforts will help the health care system to take its rightful place on the frontlines of America's effort to end domestic violence and help victims.

[Whereupon, at 3:45 p.m., the subcommittee was adjourned.]

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